TECHNICAL REPORT NO. LWL-CR-05S69

A BLISTER SHEET AND POUCH OVERWRAPPER PACKAGE FOR THE IODINE WATER PURIFICATION TABLET

Final Report
Contract No. DAAD03-70-C-0089

By
Denny F. Brown
Charles T. Derick
Columbia Research Corporation
Gaithersburg, Maryland 20760

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U. S. ARMY LAND WARFARE LABORATORY
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ABSTRACT

The development and pilot production of a blister sheet and pouch overwrapper package for the iodine water purification tablet is described. The pouch measures 3 3/8" x 2 5/8" and is fabricated from a laminated film of Mylar-aluminum foil polyolefin. Inside the heat sealed pouch are two blister sheets 2 1/8" x 1 3/4" which are fabricated from 5 mil film of Aclar 22A. Each blister sheet contains one dozen iodine tablets which are isolated from one another and the environment by a heat sealed gridwork. A pressure sensitive label applied to the back of each blister sheet contains the use instructions on one side while its adhesive side, seen through the transparent blister is colored a potent tablet matching gray. Because the iodine tablet discolors as it deteriorates, this gray background serves as a tablet color gauge for determining which tablets are potent or impotent. Approximately one hundred ten thousand (110,000) blister sheets sealed in fifty-five thousand (55,000) pouches were fabricated. These in turn were packed in intermediate boxes and shipping cartons and sent to the U.S. Army for their laboratory and field testing.

SUMMARY

The iodine tablets currently in use by the U. S. Army for the purification of water are packaged in a small glass bottle, which provides insufficient protection of the contents once opened. Because of the need for a new and improved package, a development and pilot production effort was undertaken by Columbia Research Corporation under Contract No. DAAD05-70-C-0089 with the U. S. Army Land Warfare Laboratory (USALWL). The new package that has been developed consists of a pouch, 3 3/8" by 2 5/8", made from a laminated film of Mylar-aluminum foil-polyolefin. Inside the pouch are two blister sheets, 2 1/8" by 1 3/4", made from 5 mil Aclar 22A film. Each blister sheet contains 12 tablets, with each tablet isolated by a heat sealed gridwork. Advantage is taken of the fact that degradation of the tablets, due to their contact with humidity or otherwise, is generally indicated by discoloration. The adhesive side of the instruction label applied to the back of the blister sheets has the same color as that of potent tablets. Therefore, the user can easily eliminate those tablets that have lost potency, if any, by comparing the color of the tablet with that of the label as seen through the transparent packaging material. The proper combination of temperature, sealing time, and pressure was determined to permit satisfactory sealing of the Aclar film -- a packaging material having unusual physical characteristics. Similarly, new methods for quality control and testing were developed, so as to eliminate, during the developmental process, those blister packs which did not provide an adequate barrier against degradation. A pilot run of 55,000 pouches was produced. These, in turn, were packed in intermediate boxes and shipping cartons for delivery to laboratory and field testing sites. The advantage of the new package over the glass bottle appear to be the following:

Individually isolated tablets
Immediate field indication of tablet potency
More convenient shape (flat)
Reduced weight (60%)
More legible and informative instructions for use

The material cost for the new package in production is estimated to be $0.12 per pouch of 24 tablets, of which one-half represents the cost of the tablets themselves. Titration testing of completed packages exposed to humidity testing has demonstrated the ability of the package to protect the contents from simulated environmental conditions. It is recommended that serious consideration be given to adopting this package design for future procurements of iodine water purification tablets.

ACKNOWLEDGEMENT

Columbia Research Corporation wishes to acknowledge the considerable technical assistance and guidance provided by Mr. Joseph Carney of the U. S. Army Land Warfare Laboratory during the design and production phases of this project.

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INTRODUCTION

The current standard issue of iodine water purification tablets consists of a 115 milligram tablet containing 18 percent tetraglycine hydroperiodide as the active ingredient. The tablet, although effective as a water disinfectant, loses potency readily when exposed to moisture or through sublimation of the iodine vapor. The tablet, because of its iodine content, is highly corrosive to most of the common packaging materials. These problems are particularly acute in a hot, humid environment.

The container presently in use is a small 50 tablet glass bottle which has a fiberglass pledget with screw enclosure. A wax dip around the cap threads forms a secondary seal. Uncapping of the bottle destroys the wax seal and releases the equilibrium iodine vapor pressure and permits the intrusion of potentially moist air from the surrounding environment. Consequently, a large percentage of the unused bottled tablets are rendered impotent when this occurs.

The U.S. Army Land Warfare Laboratory (USALWL), recognizing the inadequacies of the bottle, contracted with Columbia Research Corporation (CRC) to develop a flexible package containing individually sealed tablets in a blister sheet, which are then further sealed in a pouch overwrapper. A pilot production of the finalized package containing the iodine tablets, which were to be subjected to extensive U.S. Army laboratory and field testing, was also required.

This final report includes: (a) the contract objectives; (b) a description and evaluation of the developmental processes; (c) a delineation of the manufacturing procedures used in fabrication of the pilot production quantity of packages; (d) an evaluation of the packaging and fabrication techniques; (e) a discussion of the package's particular features; (f) suggested improvements to fabrication techniques utilized on the pilot production to make them more suitable for mass production operations; and (g) conclusions and recommendations.

OBJECTIVES

The design and production objectives are listed below in the following order: blister sheet, pouch overwrapper, intermediate boxes, and shipping cartons:

BLISTER SHEET

1. Film - Aclar* or Aclar lamination (Aclar must be in contact with tablet).
2. Size - 1 3/4" x 2 1/8".
3. Arrangement - twelve blisters per sheet in 4 x 3 units, tear notches opposite each outside tablet.
4. Sealing - each tablet isolated by a heat sealed gridwork.
5. Life - two-year shelf life when sealed in overwrapper and a six-month operation life when overwrapper is opened under hot-wet environment.[1]
6. Tablet Potency Gage - a gray colored background matching the color of a potent tablet when viewed through the transparent blister.
7. Labeling - directions for use on the back of each blister sheet, arranged as shown in Figure 1.
8. Tablet Air Exposure before Packaging (maximum) - five minutes at an absolute humidity of 7.59 grams/(meter) (corresponds to 30 percent relative humidity at 80°F).
9. Quantity Required - 110,000.

*Allied Chemical trade name for their fluorohalocarbon film

1 Superscript numbers indicate references listed on page 38.

POUCH OVERWRAPPER

1. Film - lamination of 0.5 mil Mylar/0.35 mil aluminum foil/ 3 mil C79 polyolefin (Continental Can Corporation).

2. Contents - two nested blister sheets with the blisters facing each other.

3. Life - to provide a two-year shelf life to blister sheets under a hot-wet environment.[1]

4. Color - olive drab exterior surface.

5. Labeling - see Figure 2.

6. Quantity required - 48,000.

INTERMEDIATE BOX

1. Material - Paperboard.[2]

2. Contents - ten filled pouches and two bottles containing fifty tablets each.

3. Life - two year shelf life under hot-wet environment.[1]

4. Labeling - "This box contains 10 overwrapped packets and 2 glass bottles of water purification, iodine tablets, experimental"
   Manufacturer: Columbia Research Corporation
   Date Packed: 7/70.

5. Quantity Required - 5,500.

SHIPPING CARTON

1. Material - fiberboard[3] (Fed. Spec. PPP B 636E).

2. Contents - twenty filled intermediate boxes.

3. Life - two year shelf life under hot-wet environment.[1]

4. Quantity Required - 275.

DEVELOPMENTAL STUDIES

BLISTER SHEET AND OVERWRAPPER FILMS

Background

The United States Army Land Warfare Laboratory, after completing a fairly exhaustive inquiry into the various alternative packaging films for the blister sheet selected the fluorohalocarbon film, "Aclar", as that film which would most satisfactorily maintain tablet integrity. Aclar film, however, is commercially available in three types: 22A, 22C, and 33C. Types 22A and 22C are copolymers, but differ in molecular structure (i.e. 22A is amorphous and 22C is crystalline). Aclar 33C is a terpolymer and is crystalline in its molecular structure. All Aclar types are transparent in thicknesses of 2 mils or less. In thicknesses greater than 4 mils, Aclar 22C and 33C become cloudy, while 22A retains its transparency. Although it is superior to other films in chemical inertness and as a vapor and gas barrier, Aclar is much more difficult to thermoform, seal, and laminate than the more common packaging films. Certain specific production problems encountered with Aclar film will be discussed in subsequent sections of this report.

Test Samples

Several different blister films were tested at CRC to determine their suitability for fabrication into blister sheets. Their compositions are listed below and a code number has been assigned to each of them for reference purposes.

Blister Sheet Films

Code	Film Type
1	1.5 mil Aclar 22A
2	5 mil Aclar 22A
3	2 mil Aclar 22C
4	5 mil Aclar 22C
5	1.5 mil Aclar 22A/2 mil polyethylene/ 7.5 mil polyvinylchloride
6	1.5 mil Aclar 22A/2 mil polyethylene/ 1.5 mil aluminum foil

Only one overwrapper film was specified by USALWL for the blister sheets. This laminated film is comprised of 0.5 mil Mylar (polyester)/0.35 mil aluminum foil/3 mil C79 polyolefin, and is manufactured solely by Continental Can Corporation.

A Vertrod Corporation Model 9A, manually operated thermal impulse heat sealer was used to develop sealing techniques and to fabricate test samples from blister and pouch films. Accordingly, one dozen iodine tablets were sealed within each test sample. These samples were then subjected to a variety of tests described on page 12.

The configuration and composition of test samples, which have been letter coded for reference, are listed below.

Blister Sheet Film Test Samples

Identification Symbol	Configuration	Side 1 Film Code	Side 2 Film Code
A	2 1/8" x 1 3/4" blister sheet	5 (blisters)	2 (backing)
B	2 1/8" x 1 3/4" blister sheet	2 (blisters)	6 (backing)
C	2 1/8" x 1 3/4" blister sheet**	2 (blisters)	2 (backing)
D	2 1/8" x 1 3/4" blister sheet**	4 (blisters)	4 (backing)
E	3 1/2" x 3 1/2" flat sheets**	1	1
F	3 1/2" x 3 1/2" flat sheets**	2	2
G	3 1/2" x 3 1/2" flat sheets**	3	3
H	3 1/2" x 3 1/2" flat sheets**	4	4

A hot-wet environment of 100 percent relative humidity was simulated in a temperature controlled chamber containing a water bath. Two groups of test samples were fabricated and placed in separate chambers for a continuous period of two weeks. One chamber was set for a temperature of 115 degrees Fahrenheit ($115^{o}F$), the other for $100^{o}F$. Each group of samples was comprised of blister film sample Types A, C, D, E, F, G, and H. In addition, some of these types were put into sealed and unsealed pouches made from the Mylar-aluminum foil-polyolefin film lamination to determine its effectiveness as a vapor barrier.

After completing temperature-humidity tests, the tablets were observed for discoloration. They were then titrated to determine quantitatively the amount of iodine retained according to procedures outlined in Military Specification MIL-W-283F[4]. Each tablet had to yield not less than 7.6 milligrams

** The above samples were also placed in both sealed and unsealed pouches for tests.

nor more than 9.00 milligrams of titratable iodine to be acceptable under the specification. Figure 3 shows some of the laboratory apparatus used for the titration tests.

Description of Tests

Vacuum leakage tests were conducted to determine seal integrity. For these tests, blister sample types A, B, C, and D were immersed in a beaker of water which was, in turn, placed under a bell jar. Then, a vacuum pump connected to the jar applied a differential vacuum equivalent to 20 inches of mercury for a period of five minutes. This pressure differential would force the air from the blisters through defective seals. The intrusion of water would follow the emission of air through the defective seal openings, thus wetting and discoloring the tablets.

Other tests included seal inspection for pinholes, using a 50 power microscope and inspection of seal uniformity using a polarimeter. Also, a dry high temperature test was applied to sample Types C and D, which were subjected to a temperature of 155^{o}F for a 24 hour period. The tablets from these samples were then titrated as described above to determine the iodine retained.

Film Evaluations

Vacuum leakage tests indicated an appreciable seal failure incidence among Type B test samples. Seal weaknesses associated with these samples were attributed to the dispersion of sealing heat through the aluminum substrate in the backing sheet. To make even a marginal seal required a five-second heating period on the Vertrod Model 9A heat sealer, while a period between one

and two seconds sufficed for the other sample films.

Film No. 5 used in fabrication of Type A blister samples had a number of objectionable points. These included: (a) a high tear resistance because of its 10.5 mil thickness; (b) scorching of the PVC laminate during sealing; (c) and most objectionable of all - the turning of the initially transparent blisters to a cloudy opaque white upon cooling after the humidity tests, thus making tablet inspection impossible. However, further testing revealed that cloudiness also occurred on Type A samples without tablets, thus obviating the possibility of their role as a causal factor in the clouding process. The cloudiness most probably was caused by reaction of entrapped water vapor between film laminates with lamination adhesives.

Test samples fabricated from Aclar 22A required less heat to seal and were more transparent than Aclar 22C samples. Aclar 22C, however, demonstrated higher dimensional stability than Aclar 22A.

Figure 5 presents the titration test data from samples which were exposed to temperature-humidity and dry high temperature testing. The data have been reduced to show the average titratable iodine per tablet. Parenthetically, it should be noted that the quantity of iodine measured is dependent on tablet size as well as on the state of its deterioration. In this regard, after weighing a random sampling of tablets, a mean deviation of 5 percent from the mean tablet weight of 115 mg was indicated. Some of the data scatter in Figure 5 is probably attributable to tablet weight variations.

Conclusions based on the Figure 5 test results appear below:

1. Aclar 22A and Aclar 22C afford approximately equal protection in containing the iodine in the water purification tablet.

2. The degree of tablet protection is proportional to Aclar thickness.

3. The sealed pouch is also beneficial in containing the iodine within the tablet. However, once the pouch is opened, its protective effect is questionable.

4. Pill deterioration from humidity tests can be observed by a change in color that progresses from gray to olive drab and finally to yellow and orange. Deteriorated tablets take longer to dissolve in water than do fresh tablets.

5. Individual tablets vary from a mean weight of 115 milligrams by $\pm$ 5 percent. Tablet size variations contribute to the dispersions in the titration tests.

6. All test samples, with the exception of several unpouched samples using 1.5 and 2.0 mil thick Aclar, met the minimum requirement for each tablet containing at least 7.6 milligrams of titratable iodine per tablet.

7. All test samples had satisfactory seals (i.e., material would tear before seal parted).

8. Aclar 22A is superior to Aclar 22C in that it requires less heat for sealing, has greater clarity in 5 mil or greater thicknesses, and laminates more easily to other types of plastics.

BLISTER FORMING

Forming Machinery

Blisters from Aclar film were fabricated on a Packaging Industries, Sentinel Model JF-914 Blister Forming Machine, Figure 4 shows a photograph of this machine. In operation, this machine feeds a roll of film through it by

engaging film edges with pins attached to a moving chain. Then the film is passed beneath ceramic radiant heaters to reduce it to a plastic state. From here it proceeds into the water heated male vacuum mold where blister forming occurs. Following blister forming, the film moves to a trimmer which removes its edges and thence to a shear which cuts the roll into individual sheets of blisters.

Mold Design

The JF-914 male vacuum blister forming mold was designed to fabricate blisters with certain desired qualities such as: a) fabrication ease; b) tablet filling ease; c) uniformity of blister film thickness; d) support resistance against breakage of packaged tablets; e) and tablet accessibility by hand tearing. Figure 6 shows the design drawing of one of two identical sections of the forming mold, which are mounted abreast of each other in the JF-914. Phantom lines, in the plan view, outline the size and position of the final die cut blister sheets. A drawing of the blister sheet produced by the mold is shown in Figure 7.

Micrometer measurements of formed blisters revealed no film thickness variations while filled, and sealed blister sheets gave snug support to tablets. In production, blister fabrication and tablet filling operations ran smoothly, provided that the machinery was properly adjusted. Tablet accessibility by hand tearing blisters was deemed satisfactory.

Forming Properties

Blisters were formed from film Types 2, 3, and 5 (page 10). The following machine settings and adjustments are recommended for the JF-914 for forming:

1. Mold Temperatures - 100° to 105°F
2. Blister Forming Period - 6 seconds
3. Ceramic Heaters - positioned 8 inches above film
   - temperature control dials set at 70 (temp. relation unknown)

Type 5 film was the easiest of the various films to form since the polyethylene and polyvinylchloride laminates in it permit higher tolerances in machine settings for satisfactory forming. This film, however, failed as a packaging material in tests described earlier.

Film Types 2 and 4, comprised entirely from Aclar, were much harder to form into blisters. The major problem with these films was that malformed blisters resulted from small variations in the machine parameters. For instance, if the ceramic heaters became too hot, material foldover occurred in the mold during drawdown; if temperatures became too cold, incomplete blister forming resulted. In a similar manner, mold temperatures slightly hot caused inverted blisters, while a temperature slightly cold caused incomplete blister forming. The daily temperature variations in the building were also a factor that continually necessitated minor machine adjustments to produce good blisters. In addition, variations in the Aclar film required frequent machine adjustments during forming. This factor is discussed in detail on page 28.

GRAY BACKGROUND COLOR MATCH

Concepts

The initial effort to provide the blister sheet gray background color match was to color the film backing sheets. To pursue this concept, General Felt Products Corporation was solicited to produce samples of Aclar film with a

tablet matching gray coloring. Because Aclar film characteristically rejects inking, their approach was to laminate other types of film to the Aclar which would then be colored.

Two laboratory samples were submitted by General Felt Products to CRC for evaluation. The first sample consisted of a film lamination of 1.5 mil Aclar 22A/gray adhesive/2 mil polyethylene. The second sample consisted of a lamination of 1.5 mil Aclar 22A/clear adhesive/0.5 mil Mylar/gray ink. Both samples proved unsatisfactory in color stability when the gray color turned to a maroon after having been subjected to temperature-humidity testing. Another unsatisfactory feature of the sample containing the Mylar and outside inking was ink removal along the seal. In addition to these technical shortcomings, a price quote of $12.25 per pound for fabricating a laminated film of one of the above types was considered excessive.

The second approach was an attempt to locate a commercial pressure sensitive label stock with potent tablet gray coloring facing its adhesive side. The label then would be applied to the back of blister sheets, to provide the color match, while the use instructions would be printed on the reverse side. After an extensive search, one acceptable label with a suitable tablet matching gray color was finally located. This material was the Model No. 700 Acetate Fiber Tape produced by the Minnesota Mining and Manufacturing Corporation (3-M). Unfortunately, since its production had been discontinued, it was unavailable in the required quantity.

The final concept was to select a pressure sensitive clear acetate label stock and to color it first with a potent tablet matching gray, and then with

a lighter ink color. This would be followed by printing the use instructions in black ink. When the label was applied to the back of the blister sheets, the matching potent tablet gray color would show through the blister, while the use instructions on the reverse side would be legible against the lighter background coloring. In competitive bidding with other label manufacturers, the Allen Hollander Company was selected to produce 20,000 (1,666 excess for spares) pressure sensitive labels for uncut blister sheets. Each label was to contain a gray background potent tablet color match and six sets of use instructions spaced for die cut blister sheets.

Label Design and Fabrication

Figure 8 shows a photograph of the finished label measuring 2 1/2" x 12 3/4". It was fabricated from 2 mil thick, 13 1/2" x 13" sheets of a Fasson Corporation acetate label stock, having their XS 232 acrylic adhesive. Using a Heidelberg Eastern Corporation letter press, the sheets were put through six printing operations. In respective order, the process consisted of the application of two coats of tablet matching gray (HC-118-200 opaque gray), a primary coat of blue-white, a coat of silver, a secondary coat of blue-white, and finally the printing of the use instructions in black ink. The inking processes were such that two gray coats were needed to produce a uniform gray coverage. The secondary blue-white coat provided the contrasting background for the black lettering. A silver coat was added to give opaqueness to the label, and a primary coat of blue-white between the gray and silver coatings was required to preserve the matching gray color (the gray ink was matched for the

blue-white coating). Following the inkings, the sheets were slit into five smaller sheets forming the labels as shown in Figure 8.

TABLET FILLING OF BLISTER SHEETS

Requirements

To produce the pilot quantity of 110,000 blister sheets required the depositing of over 1.3 million tablets, supplied from bottles of 1,000 tablets each, into the blisters. Specifications dictated that the filling and the sealing of the tablets in blister sheets be performed in a low humidity environment with a maximum of five minutes air exposure of tablets. Also, all excess dust and broken tablets had to be removed before loading the tablets into blister sheets.

To satisfy these conditions, an automatic tablet filler was developed by CRC to integrate with a Packaging Industries F-20 Impulse Heat Sealer. This tablet filler comprised part of the semiautomatic filling and sealing system described below.

Equipment Design and Principles of Operation

The tablet filler is designed to fill all 72 tablets simultaneously into a blister sheet supported in the lower half of a sealing tray made to integrate with the F-20 heat sealer. When in operation, the tray is hand shuttled between the filler and sealer. Figure 9 shows a photograph of the automatic tablet filler with the sealing tray in the load position. Figure 10 shows a second view of the system which includes the F-20 Impulse Heat Sealer.

The operational sequence begins with loading of tablets into Syntron Model EB-00 Parts Feeder. Vibratory action propels tablets along a spiral ridge

within the bowl into four counting tubes, each containing 18 tablets. Once all the tubes are filled (i.e., all 72 tablets), the remaining tablets fall back into the bowl and continue to circulate. Slots cut in the bowl wall allow the unwanted dust and broken tablets to escape.

When activated, a pneumatic piston connected to the unit of hinged counting tubes swings these tubes clear of a gate to eject tablets onto an aluminum four-channeled template. At the same time, an air jet located in the bowl downstream of the counting tubes blows circulating tablets back into the bowl before they can reach the now opened filling tubes. When the piston is deactivated, the tubes return to their former position, the air cuts off, and another load of tablets refills the tubes.

The four-channel template is bolted to an overhead mounted Syntron F-T01 Vibra Drive, which, like the parts feeder, uses vibration action to propel tablets. Spaced along the bottom of each channel are eighteen 0.30" diameter holes arranged in a pattern that matches the blisters in the blister sheet. The holes are closed off or opened up by a spring loaded sliding gate mounted beneath the template. Following ejection from the counting tubes, the tablets are vibrated into the closed off holes along each channel. When the sealing tray is slid beneath the template, it triggers the gate, thus causing all tablets to simultaneously drop into the blisters which are aligned in the tray underneath the template. When the tray is withdrawn, the gate closes, and the template is ready for another load of tablets from the counting tubes.

PRODUCTION HEAT SEALING EQUIPMENT

Description of Equipment

The two part sealing unit comprised of two trays was designed to make heat seals from both sides of the blister sheets when incorporated with the Packaging Industries Model F-20 Impulse Heat Sealer. The lower tray supports the blister sheets and is shuttled by hand along rails between the F-20 and the tablet filler while the upper tray mounts in the F-20 on the pneumatically actuated overhead plate.

The rectangular tray bases are constructed from 5/8" thick phenolic. The upper one measures 12" x 22 1/2" , and the lower one measures 14 1/2" x 22 1/2". Sealing elements are glued to the trays and constructed from a 4 mil thick nickle-iron alloy. This alloy is photo-etched to make seals 3/32" wide and arranged in a pattern to make multiple parallel seals between and along the outside edges of the blisters. Power for the sealing elements is supplied at a 40-volt potential from the F-20 through the electrical contacts and wires incorporated in the tray. A 5 mil teflon pressure sensitive sheet is applied over the elements to prevent them from sticking to the blister sheets.

The sealing elements of both trays are arranged to make longitudinal seals on one side of the trays and transverse seals on the other side. Therefore, two sealing operations are required to make a gridwork of seals around the blisters. In operation, longitudinal seals are made first, followed by movement of the sheet to the second station on the lower tray where the transverse seals are made.

Sealing Operation and Discussion

When the lower tray with unsealed blister sheets is shuttled into the F-20, the pneumatically actuated upper tray is forced down under pressure to the lower tray, thus sandwiching the blister sheets in between. Upon application of pressure, a switch activates power to the sealing elements for a fixed time interval which is set by an adjustable timer. The trays continue to be held together following the cutoff of power to permit seal cooling under pressure for a specific time interval which is set with a second timer. Following this operation, the top tray is automatically retracted, thus permitting withdrawal of the lower tray which contains sealed blisters. For optimum operation, the following Sentinel Model F-20 Impulse Heat Sealer machine settings are recommended:

1. Pressure Switch - 35 psi
2. Heating Timer - 1 1/2 seconds
3. Cooling Timer - 6 seconds

Numerous problems arose during sealing operations which had to be solved before a satisfactory system was attained. Foremost among these problems was the burnout of sealing elements in trays on six separate occasions. Each burnout shut down the production operations until tray repairs were made. Element failures were attributed to hot spots in elements resulting from cross-sectional variations. Closer tolerances in manufacturing sealing elements of more uniform cross-section finally eliminated the burnouts. The Teflon (polytetrafluoroethylene) pressure sensitive sheets required frequent replacement because of wear caused by its sticking to the Aclar blister sheets. This effect

required hand removal of the blister sheets stuck to the trays and slowed the production rate. Although the cause of sticking was not resolved, it is interesting to note that Teflon and Aclar are both chemically of the fluorocarbon family, which may be a clue in explaining their mutual affinity.

Bad corner seals were evidenced on occasion and were caused by pressure loss resulting from sealing tray warpage. This problem was eliminated by shimming and adjusting the upper tray mounting bolts to produce an even pressure distribution. Seals became marginal if the tray became too hot from repeated heating cycles because the high temperature prevented cooling of the seals under pressure, a necessary operation in heat sealing Aclar. A fan added to blow on the upper tray,where the heat retention was especially high, helped to meliorate this effect.

Attempts to reseal blisters with defective seals were unsuccessful. Design of the trays was such that sufficient pressure could not be reapplied on the second sealing attempt resulting from a film thickness reduction along seals caused by heating during the first sealing.

BLISTER DIE CUTTER

Design

Figure 11 shows the cutting die for cutting sealed blister sheets into smaller sheets of the specified size of 2 1/8" x 1 3/4" with each cut sheet containing one dozen tablets. SAE 1095 rule steel is used in the cutter blades which are then mounted in a wooden and steel base. The blades are formed to cut tear notches 0.040" deep opposite each outside tablet.

Operation

The cutting die was used with the USM Hytronic Die Cutting Machine shown in Figure 12, where the cutting operation is being performed. In operation, the uncut sheets are placed with the blisters face down in the die. The head of the die cutting machine, having a rubber composition pad, is then swung into position over the die and hydraulically activated downward to apply the pressure required for cutting each large sheet into the six smaller sheets of the specified size.

POUCHING OF BLISTER SHEETS

Pouch Design

Individual pouches fabricated from the specified lamination film of 0.5 mil Mylar/0.35 mil aluminum foil/3 mil C79 polyolefin were supplied by the film manufacturer, Continental Can Corporation. A photograph of the pouch as fabricated is shown in Figure 13 along with two blister sheets. The pouch measures 2 5/8" x 3 3/8" and has 1/4" wide heat seals along three of its edges. The fourth edge is left unsealed for hand filling of two nested blister sheets. Tear notches are provided along edges of the pouch to facilitate its opening when sealed. Because of the relatively low quantity order, flexographic printing methods were used to color and label the pouches externally on the Mylar. To prevent ink removal during sealing, edges of the pouches were left uncolored. In large production quantities, which would justify the added expense, the Mylar would be reverse printed on the inside face of mylar adjoining the aluminum laminate to eliminate the problem of ink removal, thus permitting total coloring.

Filling and Sealing

Each pouch is filled with two blister sheets, the blisters facing each other and nested. Figure 14 shows this operation being performed.

The filled pouches were heat sealed by using a Doughboy Model HS-B heat sealer, modified at CRC with a pouch sealer guide for this particular operation. A photograph of the sealer with the pouch guide is shown in Figure 15.

In operation, the sealer engages the open lips of the pouch between two motor driven chains moving at 200 inches per minute. While the engaged pouch is moving with the chain drive, heater bars arranged parallel to the chains are set at 450°F to heat the lips of the pouch. At the far end of the sealer, the pouch lips are pressed together under pressure by two serrated rollers to form the seal.

Pouching Evaluation

The pouching film proved easy to heat seal, and its protective effect to the tablets was established during film studies. The film, however, tends to curl on heat sealing because of the different expansion coefficients among the laminates and may be a problem with some production equipment. Because of the Mylar substrate in the film, it cannot readily be torn by hand without a tear notch.

Although the film material had beneficial attributes, the pouches furnished were fabricated in a somewhat shabby manner. Examples of poor workmanship included a large variation in color among pouches, fuzzy printing, tear notches placed in the wrong position (they were supposed to tear along the short dimension), inadequate seals (the entire shipment of pouches had to be returned to

Continental Can Corporation for resealing), and a large number of pouches rendered useless by improperly placed seals (3/8" up from the bottom, making them impossible to fill with blister sheets and make the fourth seal).

The Doughboy Heat Sealer formed serrated fourth seals of high quality which admirably passed the standard test of suspending a 50 oz. weight from a one-inch strip containing a seal for five minutes. When manual destruction was attempted, the material tore before the seal parted. For aesthetic reasons, however, the package would look more appealing with all heat seals of one type.

PILOT PRODUCTION OPERATIONS

GENERAL

A number of production functions were required to produce the specified quantity of one hundred ten thousand (110,000) blister sheets in overwrappers. These functions are listed below in the chronological sequence in which they were performed:

1. Forming from rolls of Aclar 22A film, twenty-two thousand (22,000)*** sheets of blisters measuring 3.5" x 13".

2. Shearing from rolls of Aclar 22A film twenty-two thousand (22,000) backing sheets measuring 2.5" x 13".

3. Filling and sealing 1.3 million iodine tablets in the produced blister and backing sheets.

4. Applying twenty thousand (20,000) labels to the sealed blister sheets.

5. Die cutting the labeled blister sheets to make in excess of one hundred and ten thousand (110,000) blister sheets containing one dozen tablets each.

6. Hand filling and sealing one hundred and ten thousand (110,000) blister sheets into 55,000 pouches.

7. Erecting and filling fifty-five hundred (5,500) intermediate boxes.

8. Erecting, filling, and stapling shut two hundred fifty (250) shipping cartons.

The relatively low production quantity did not justify use of highly automatic machinery which would incur high initial setup expenses. Instead, many of the tasks were performed with machinery of limited capacity or by hand.

***Excessive quantities were produced to account for production rejects.

FORMING BLISTERS

Blister sheets were formed from rolls of 5 mil thick Aclar 22A film manufactured by Allied Chemical. The film was supplied in seven rolls, each roll 15 1/4" wide, approximately 1,000 feet long, and weighing 100 pounds. Between two and four spliced lengths were observed in each roll. Blister forming operations were consummated in eight working days by using a machine operator and a production worker who stacked the sheared blister sheets in boxes.

The Aclar film exhibited different forming characteristics among the various spliced lengths, which necessitated continual adjustments to the JF-914. Examination of the film revealed variations among spliced lengths of film in flexibility and film thickness (one spliced length measured 3.5 mil). In addition, several spliced lengths contained embedded grit and other foreign matter. Because of the incompatability between these variations and the required close machine tolerances, 30 percent of the Aclar film was wasted in malformed blisters.

BACKING SHEETS

Backing sheets were cut from rolls of 5 mil thick Aclar 22A film, 14 inches wide and corona etched on the outside. Corona etching is a process of electrostatically roughing the surface of a film to give it better adhesive characteristics (e.g., in this case, pressure sensitive labels). Because the etching is not visually discernible, it was necessary to stack the cut sheets in a consistent orderly manner after they were sheared. A JF-914 identical to the one for blister forming, but with its forming equipment inactivated, was used to shear backing sheets. All twenty-two thousand (22,000) backing sheets were cut in three

working days by using a machine operator and one production worker to stack the cut sheets.

FILLING AND SEALING

Filling and sealing operations were performed in a room maintained at low humidity according to the aforementioned contract objectives. Humidity readings taken daily with a sling psychrometer, showed a relative humidity level of 35 percent at 72°F. In absolute humidity units, during the period of filling and sealing, this value corresponded to 6.00 grams of water per cubic meter of air (6.00 gr/m^3), and was well within the specification requirement of 7.59 gr/m^3.

A low humidity environment, in addition to being necessary for the maintenance of tablet potency, was also necessary to keep the automatic tablet filler machinery from fouling. Attempts to run the tablet filler in high humidity caused tablet deposit build-up in the counting tubes and template holes, thus reducing clearances to a point where they would not accommodate tablets. When this occurred, a thorough cleaning of holes and tubes with a wire gun-brush was required to restore the filler to an operating condition. However, cleaning of deposits was unnecessary if the air was kept within the low humidity specifications.

The filling and sealing task took 26 working days using both a machine operator and a production worker. Because of wasted time caused by burnouts of sealing tray elements, this operation was spread over a three-month period between May and August of 1970. Considerable additional expenses were accrued with sealing tray burnouts. These expenses were manifestations of unproductive

labor costs, costs for tray repairs, and the costs for purchase of a second backup sealing tray. It is estimated that such expenses amounted to approximately five thousand dollars ($5,000).

When the sealing and tablet filling machinery was being operated smoothly by experienced personnel, between 50 and 60 thousand tablets were filled and sealed daily. This quantity of tablets corresponded to between four and five thousand die cut blister sheets of one dozen tablets each. The rate of production was limited by a long sealing cycle of approximately ten seconds. During filling operations, it was noted that approximately 10 percent of the iodine tablets in the sealed one thousand tablet bottles contained tablets with yellow spots. Although an attempt was made to remove these tablets during the filling operations, the spots often were visible from one side only; and, consequently, a large number were loaded and sealed in blisters before detection.

LABEL APPLICATION

Labels were applied to the 20,000 uncut blister sheets by using two production workers over a 10-day period. Once personnel became proficient in the hand application of labels, two production workers could apply 2,600 labels daily. This application rate corresponded to over 15,000 cut blister sheets daily.

In mass production, labels could probably be machine applied at a much faster rate. In addition, this function could probably be done on line following filling and sealing operations, thereby effecting a reduction in labor cost.

DIE CUTTING

The die cutting of the 20,000 labeled, filled and sealed blister sheets to make 120,000 notched sheets of one dozen tablets each took 10 days, using

a machine operator to operate the press and one production worker to separate the trimmed scrap from the blister sheets. Die cutting operations proceeded smoothly with the exception of an occasional cutting of blisters which were not properly seated in the die. When this occurred, the applied pressure from the die cutter head crushed all tablets. Crushing was most frequent with wrinkled sheets which did not lie flat in the cutting die. Approximately 1 1/2 percent of the blisters were crushed during the die cutting process.

POUCHING AND BOXING

The 110,000 blister sheets were hand-loaded in pouches, which were then sealed and loaded in intermediate boxes and shipping cartons over a 10-day period. This work was performed with four production workers. Blister sheets were visually inspected for tablet discoloration before being packed in pouches, and any sheet containing a discolored tablet was rejected. Approximately five percent of the blister sheets were rejected in this manner. During production, a three-man force, hand loading pouches, could maintain pace with an operator feeding the filled pouches through the Doughboy HS-B Heat Sealer.

QUALITY CONTROL TESTS

Test Description

A one-half percent sample of the produced 110,000 blister sheets (550 units) in lots of 2,000 (10 units) were drawn for quality control testing purposes. Each sample of 10 sheets per lot were handled as follows:

1. One sheet from each 10 was subjected to a humidity test for five days at 115°F and 100 percent RH, followed by titration to determine quantity of the iodine content. (This involved 55 separate titrations).

2. One sheet from each 10 was subjected to immediate titration. (This involved 55 additional titrations).

3. Three sheets from each 10 were subjected to a vacuum leakage test.

4. Three sheets from each 10 were subjected to visual examination, polarimeter check, random measurement, and other manual tests.

5. The remaining two sheets were held in reserve for additional tests, if required, or for confirmation tests should the titrations indicate marginal iodine activity.

In addition to the foregoing, 240 pouches were drawn as a sample, each of which was subjected to detailed visual examination. A random 10 percent was then subjected to a vacuum leakage test. Procedures for performing tests were outlined on page 8.

Test Results

All 55 samples subject to immediate titrations passed the minimum iodine content per tablet of 7.6 milligrams. The mean value for all the samples tested was 8.25 mg. Likewise, the samples titrated after humidity tests all passed the minimum iodine requirement. However, the mean value of iodine content was reduced to 7.99 mg., thus indicating a degree of deterioration. Inspection of these samples before titrations revealed yellow spots on some tablets.

In vacuum tests, 10 percent of the blister sheets had one or more leaks (usually a single leak at one of the corners). Considering each sealed tablet a separate entity, the failure rate among all blisters was 1 percent.

Microscopic and polarimeter checks of blister sheets revealed no seal holes, and for the most part, uniform seals. Vacuum test failures are attributable

to variations in heat sealing parameters during production sealing on the Sentinel F-20 Heat Sealer. These failures were uniform in occurrence throughout production. It was difficult to tell before vacuum testing whether or not a seal would be defective.

DISCUSSION

The developed blister sheet and pouch overwrapper package for the iodine water purification tablet represents a packaging improvement over the present fifty tablet bottle. Its major advantages over the bottle are manifested in the following features: a) the individual sealing of tablets, which eliminates air exposure of tablets until used; b) its use of a tablet potency color match; c) its more convenient flat shape; and d) a weight reduction from 26 grams to 9 grams per package.

Testing at elevated temperatures and high humidity exceeding any likely actual condition which would be encountered, revealed no tablet potency loss of pouched blister sheets. However, once the pouch was opened, sustained exposure to high temperature and humidity indicated that the tablets would undergo gradual process of deterioration. The rate of tablet deterioration increased proportionally to the reduction in film thickness, increase in temperature, and duration of exposure.

Titration tests indicate color matching of tablets is conservative in gauging tablet potency. Even the almost completely yellow tablets passed the minimum requirement of 7.6 milligrams of titratable iodine, although it was noted that discolored tablets took longer to dissolve.

Seal failures, discovered in vacuum leakage tests, were attributed to variations in the heat sealing equipment. In mass production, sealing equipment would be designed to operate more reliably. In addition, sealing temperature and sealing pressure would be monitored to assure maintenance of proper and constant machine parameters.

More efficient methods of manufacturing should reduce production costs by over one half. For example, the present package sustained a scrap loss of over 50 percent in the Aclar film from trimming and die cutting operations. This fact is particularly unfortunate in that the waste cannot be reprocessed and Aclar presently costs $7.11 per pound. Reduction of the scrap rate could be effected through better arrangement of blisters.

The development of a paper label with gray adhesive should reduce label cost by at least 60 percent, while automatic machinery for application would virtually eliminate labor costs. Pouch filling and sealing costs could be cut by a similar percentage by employing a pouch forming and sealing machine. Such a machine would automatically stack two blister sheets and then form and seal a pouch around them from preprinted roll stock. An investigation of a cheaper pouching film may also be warranted to further reduce production costs.

Further cost reductions could be initiated in large quantity production by incorporating machinery to package pouched blister sheets in boxes and shipping cartons.

It is estimated that the developed package, given present material costs and with automatic machinery, could be mass produced at a cost of approximately 18 cents per package, of which 6 cents would represent the cost of the iodine tablets.

CONCLUSIONS AND RECOMMENDATIONS

1. 110,000 blister sheets containing iodine water purification tablets have been produced, sealed in 55,000 pouches suitable for field testing. This activity has demonstrated the producibility of the package design.

2. The main advantages that have thus far been recognized are the following:

    a. Each tablet is individually sealed.

    b. Any deterioration of the tablets can be easily detected visually.

    c. The pouch has a convenient flat shape.

    d. The total weight of the flexible package of 24 tablets is 1/3 that of the 50 tablet bottle used previously.

    e. The directions for use are much more legible and informative.

3. Environmental tests conducted in the laboratory indicate that the package should be able to maintain a tablet potency meeting or exceeding the specification of a two-year shelf life and six-month operational life in a wet, hot environment.

4. Quality control tests made during the pilot production revealed a 1 1/2% rejection rate due to defective seals. These defects are attributable to variations in heat sealing parameters during the production run. Improvement of the heat sealing equipment for mass production would lead to a lower reject rate.

5. The fluorohalocarbon film, Aclar 22A, used in the blister sheets requires precise control of machine parameters when it is thermo-formed into blisters and impulse heat sealed. Similarly, the pouch material must be submitted to exacting quality control, including the detection of possible pinholes.

6. The automatic blister tablet filler developed by Columbia Research Corporation for the pilot production is very reliable and virtually maintenance free. Its design has unique features which could readily be incorporated into a mass production assembly line operation.

7. The quality of the package can be improved and its cost reduced through the establishment of an automatic assembly line. Particular areas where quality and cost improvements could be significant are the arrangement of blisters in the forming operation to reduce the scrap of Aclar during trimming and die cutting; the development of a machine applied paper label; and automation of the forming and filling operations. It is anticipated that at present material and labor costs, in mass production, a pouch of 24 tablets with two blister sheets would cost about 18 cents.

8. A study should be undertaken to determine whether or not the package cost could be further reduced through the use of less expensive packaging materials. If no alternative is found for the Aclar film, then the necessary thickness of that film should be determined, since it is felt that a 5 mil thickness may be excessive.

9. In order to permit procurement of this package through competitive bidding, a complete specification package should be prepared. Some development work may be necessary in order to define certain parameters for this specification package.

10. The existing specification for the iodine tablets themselves should be reviewed, and possibly revised, in order to permit alteration of the inactive ingredients such that a more rapid dissolving rate might be achieved.

REFERENCES

1. Army Regulation AR 70-38, "Research, Development, Test, and Evaluation of Materiel for Extreme Climatic Conditions," Headquarters, Department of the Army (5 May 1969).

2. Federal Specification PPP-B-566D, "Boxes, Folding, Paperboard," (6 June 1969).

3. Federal Specification PPP-B-636E, "Box, Fiberboard," (25 June 1969).

4. Military Specification MIL-W-283F "Water Purification Tablet, Iodine," (28 December 1967), Amended 6 June 1968.

5. 1969 - 1970 Modern Plastics Encyclopedia, Vol. 46, No. 10A (October 1969).

6. Modern Packaging Encyclopedia 1970, Vol. 43, No. 7A (July 1970).

7. "Effects of Radiation on Materials and Components," Reinhold Publishing Corp., New York (1964).

SUPPLIERS AND MACHINERY MANUFACTURERS

A list of names and functions of the various manufacturers providing the basic materials and fabricating equipment used in production of the blister sheets is cited below:

Company	Service
Van Brode and Co. Clinton, Massachusetts	Iodine Tablet Suppliers
Allied Chemical Corp. P. O. Box 697 Pottsville, Pennsylvania	Aclar Film for Blister Sheets Supplier
Continental Can, Inc. 1104-5 Munsey Building Baltimore, Maryland	Pouch Supplier
L. Gordon and Son, Inc. 1050 South Paca Street Baltimore, Maryland	Intermediate Box and Shipping Carton Supplier
Allen Hollander E. 64 Midland Avenue Paramus, New Jersey 07652	Blister Sheet Label Supplier
Syntron Homer City, Pennsylvania	Manufacturer of Vibratory Units for Automatic Tablet Loader
Packaging Industries, Inc. Airport Road Hyannis, Massachusetts	Blister Forming and Blister Sealing Machinery Manufacturer
Diematic Manufacturing Co. 220 West 19th Street New York, New York	Fabricated Blister Sealing Tray and Blister Cutting Die
Doughboy Industries, Inc. 104 Grand Avenue Englewood, New Jersey	Pouch Heat Sealer Manufacturer
Fisher Scientific 7722 Fenton Street Silver Spring, Maryland	Supplier of Chemicals and Laboratory Equipment used for Titration Test

MATERIAL COST ANALYSIS

An estimate of material costs comprising the package of two blister sheets in a pouch overwrapper when it is mass produced is presented below. The estimate assumes a 20 percent scrap factor of Aclar film in trimming and die cutting operations, while no waste is allowed for the tablets, labels, and pouch overwrapper. Also, it should be noted that labor costs for production of the package are not included.

Item	Bulk Cost Rate	Cost per Package
1. Iodine Tablets	$2.50/1000	$.060
2. Aclar 22A Film 5 mil thick (i.e. 20 percent scrap) for blister sheets	$7.11/lb.	$.051
3. Label (paper)		$.005
4. Preprinted rolls of .5 mil mylar/.035 Al foil/3 mil C79 polyolefin for pouches	$0.42/1000 $in.^2$	$.004
	Total Material Costs	$.120

FIGURES

Compare tablets with background color. Do not use discolored or broken tablets.

Use tear notch to remove tablet.

DOSAGE	
Clear water:	1 tablet per quart
Cloudy water:	2 or more tablets per quart as directed.

Place tablet(s) in canteen. Replace cap loosely. Wait 5 minutes and shake, allowing leakage to rinse threads. Wait additional 20 minutes before drinking.

Figure 1. Blister Sheet Directions for Use

WATER PURIFICATION TABLETS,
IODINE, EXPERIMENTAL

This wrapper contains
24 iodine tablets sealed
individually.

Manufacturer:
Columbia Research Corp.
Date packed 7/70

(side 1)

DIRECTIONS FOR USE
Do not open wrapper until ready
to use. Keep the unused, sealed
tablets in this wrapper.

Compare tablets with background color.
Do not use discolored or broken tablets.
Use tear notch to remove tablet.

Dosage
Clear water: 1 tablet per quart
Cloudy water: 2 or more tablets per quart as directed.

Place tablet(s) in canteen. Replace cap loosely. Wait 5 minutes and shake, allowing leakage to rinse threads. Wait Additional 20 minutes before drinking.

(side 2)

Figure 2. Pouch Labeling

Figure 3. Titration Testing Iodine Water Purification Tablets

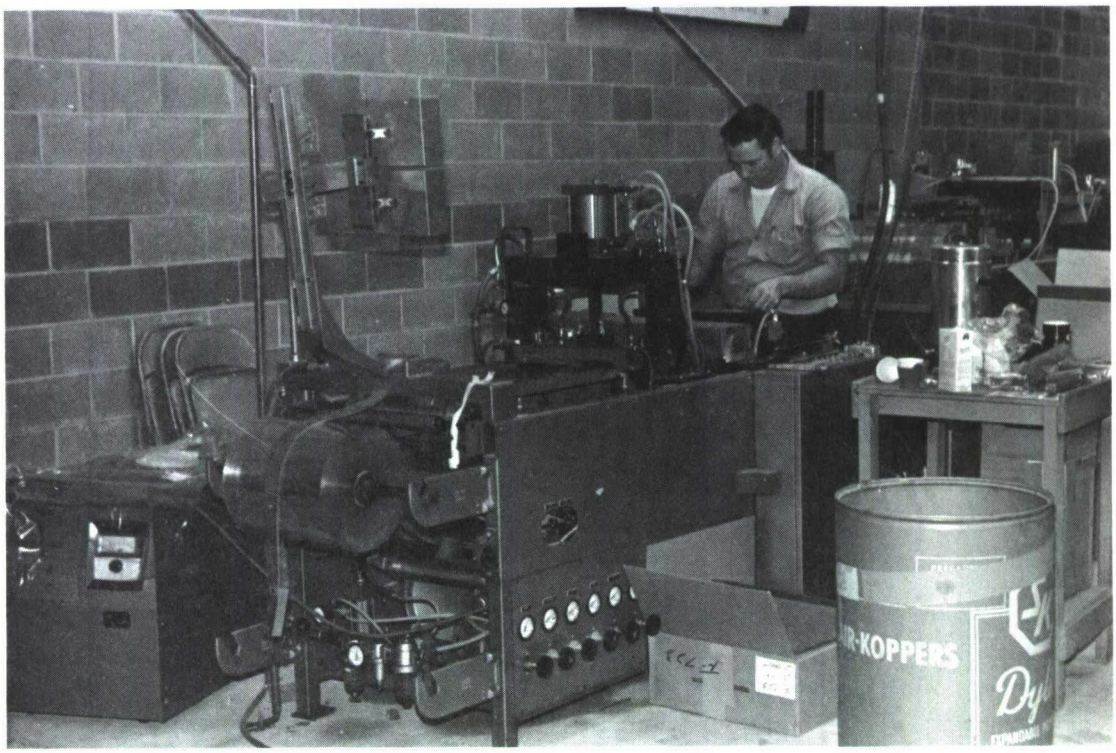


Figure 4. Forming Blisters

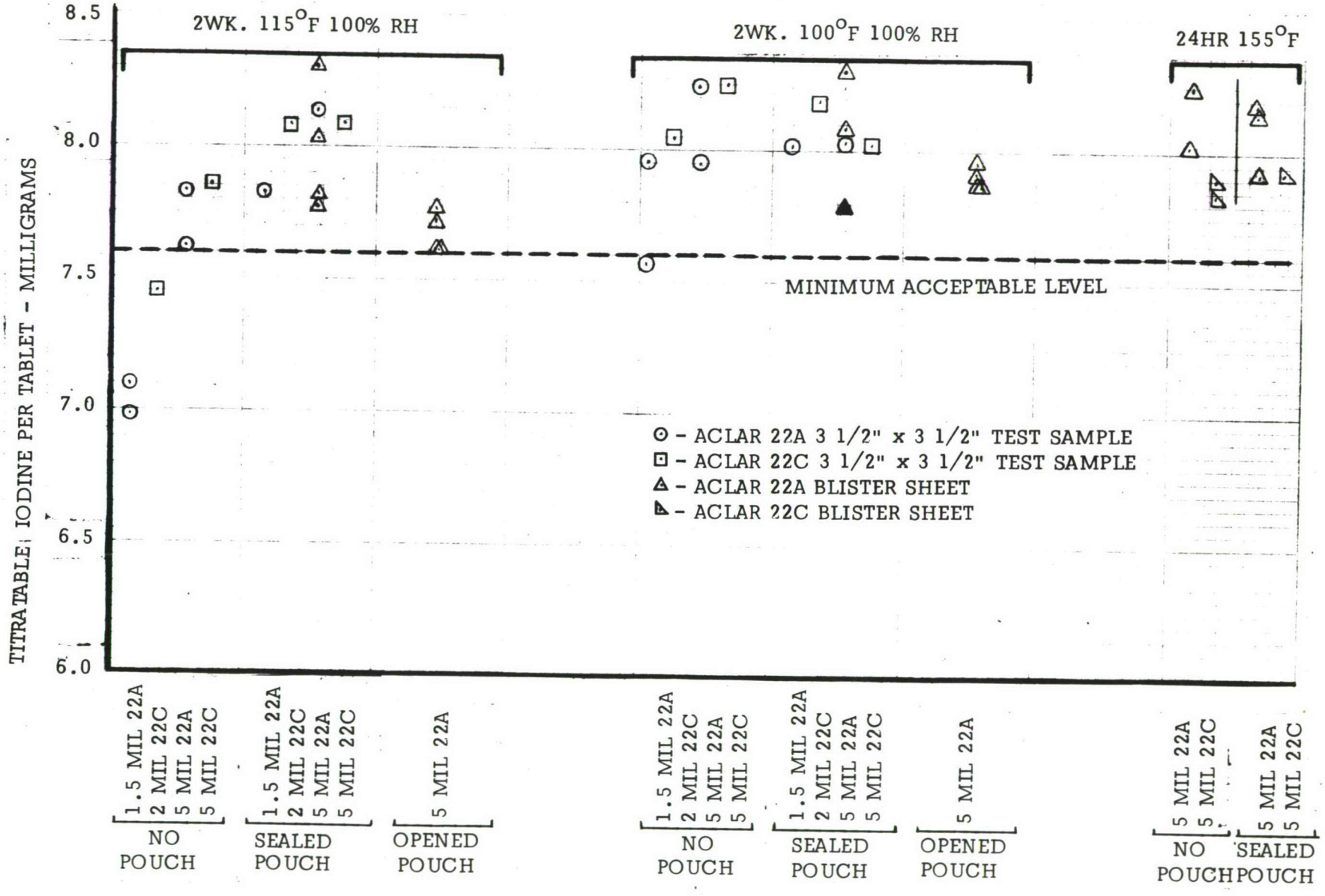
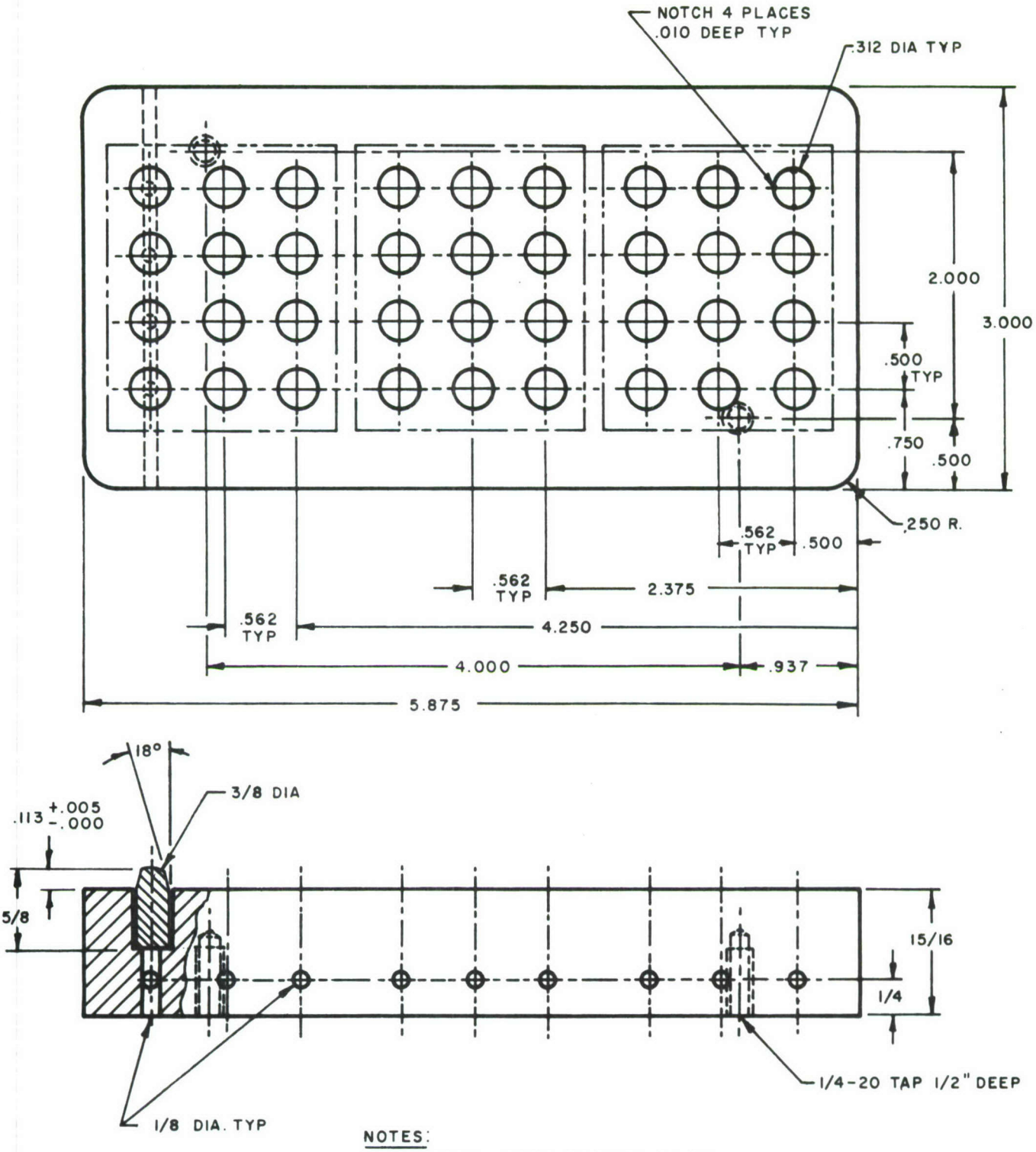


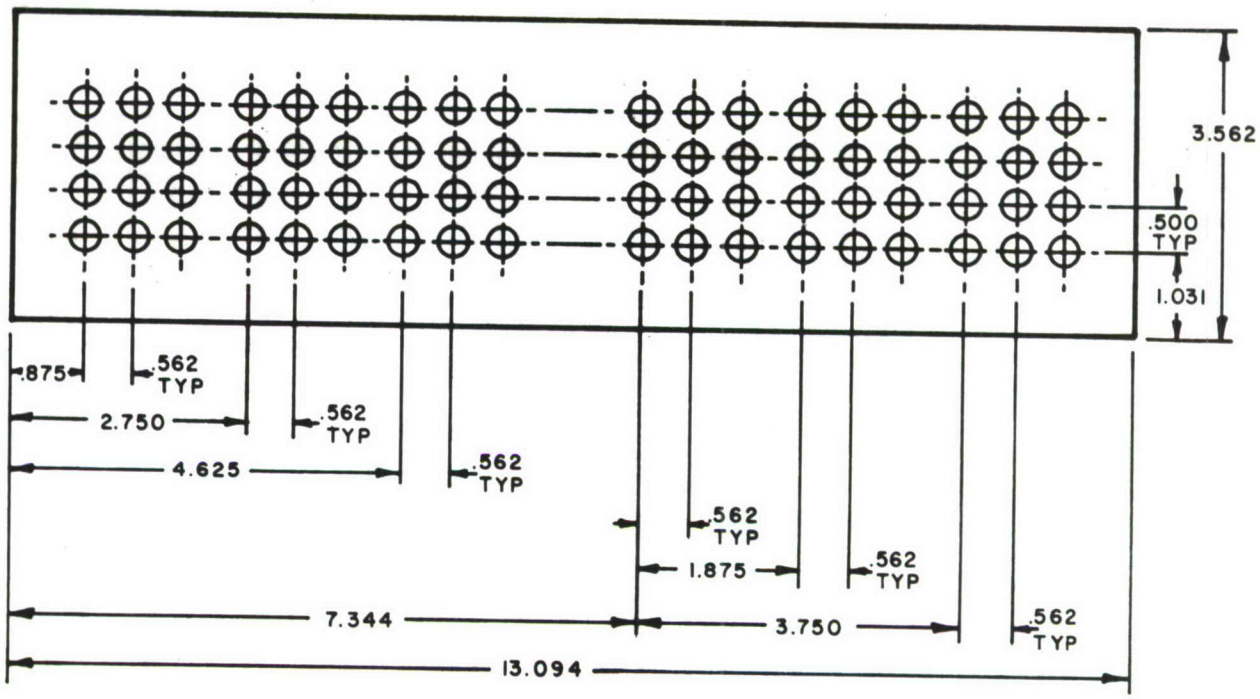
Figure 5. Water Purification Tablet Titration Tests

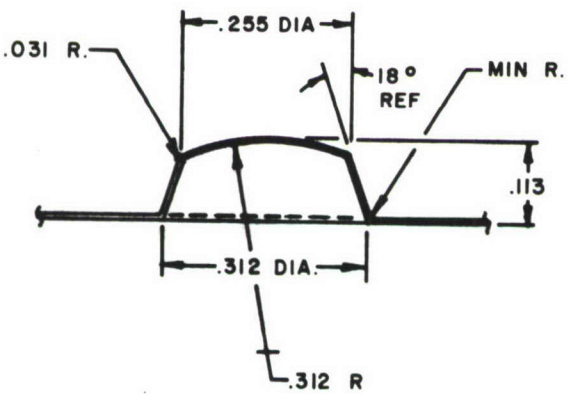


NOTES:

1. MATERIAL-2024-T4 ALUM. ALLOY
2. TOL: ± .005 & ± 1°

Figure 6. Mold Vacuum Former





TYPICAL SECTION

NOTES

1. MATERIAL: —.005 THK. ACLAR
2. DIMENSIONS APPLY AFTER MOLDING
3. TOL: ± .015 & ± 1°

Figure 7. Vacuum Formed Blister

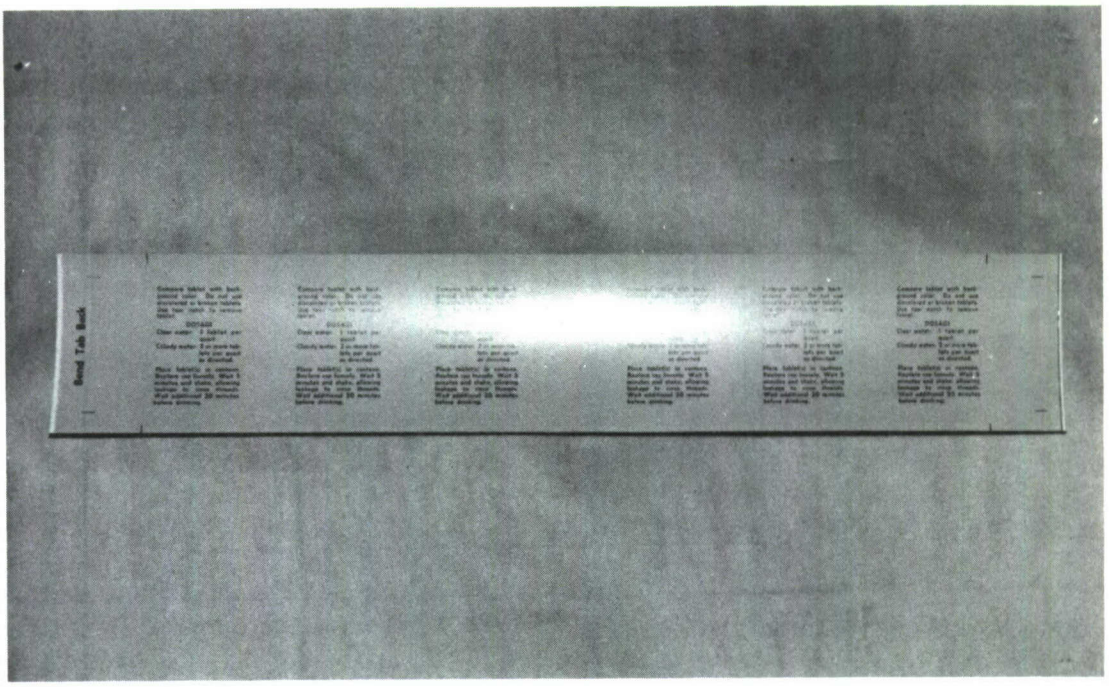


Figure 8. Blister Sheet Label

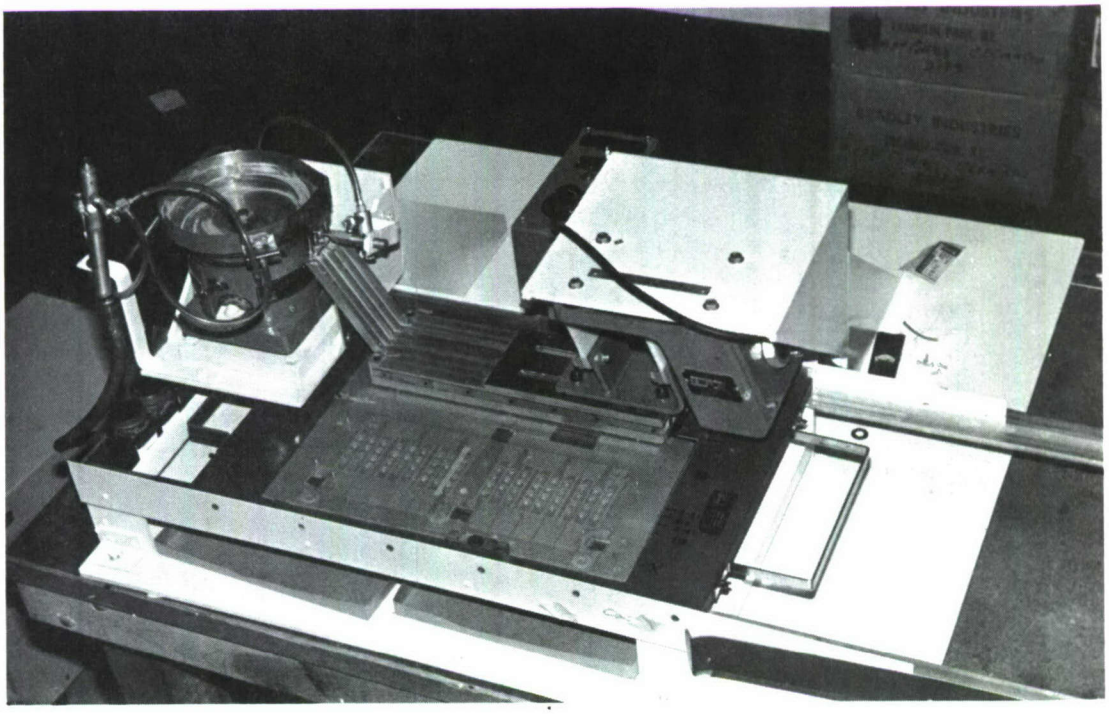


Figure 9. Automatic Tablet Filling Equipment

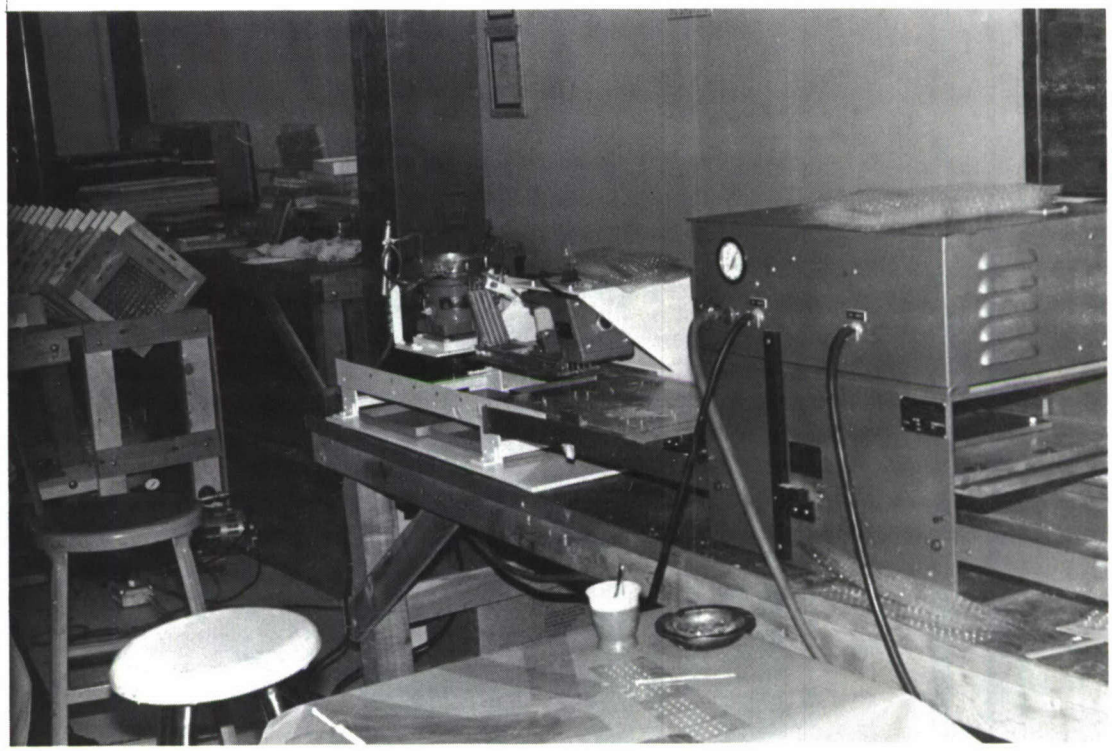


Figure 10. Tablet Filler and Blister Sheet Heat Sealer

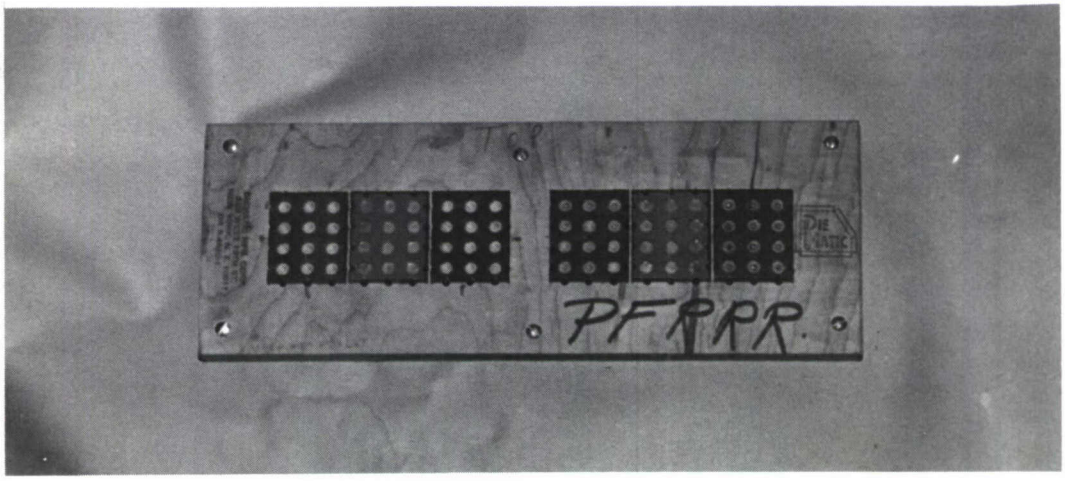


Figure 11. Blister Sheet Cutting Die

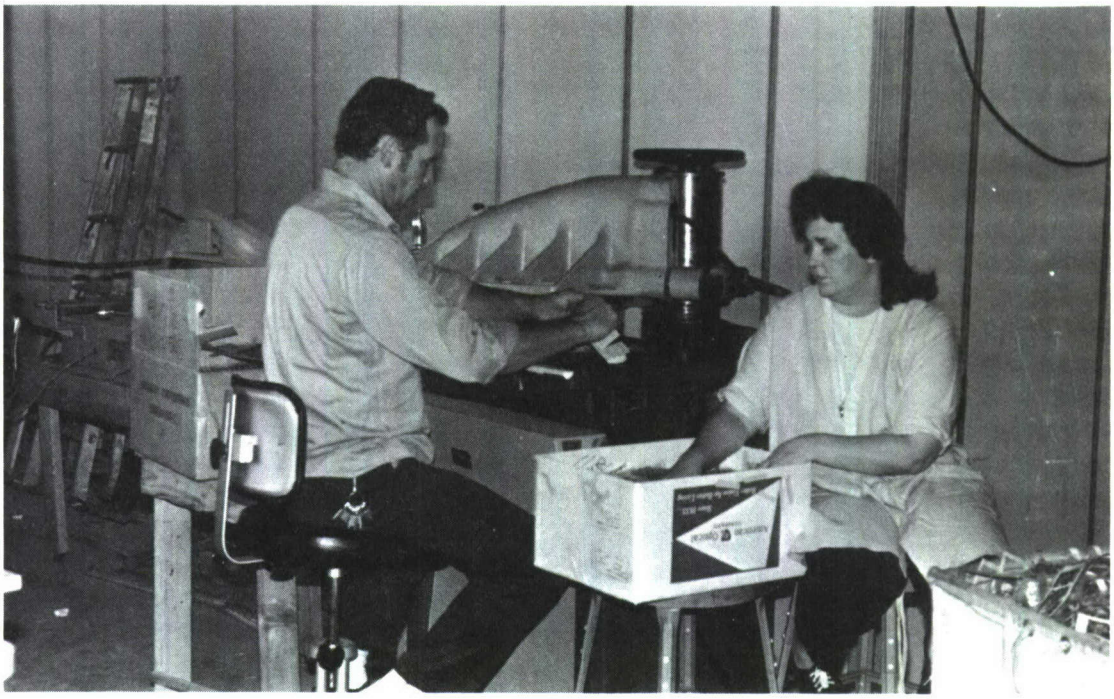


Figure 12. Die Cutting Operation

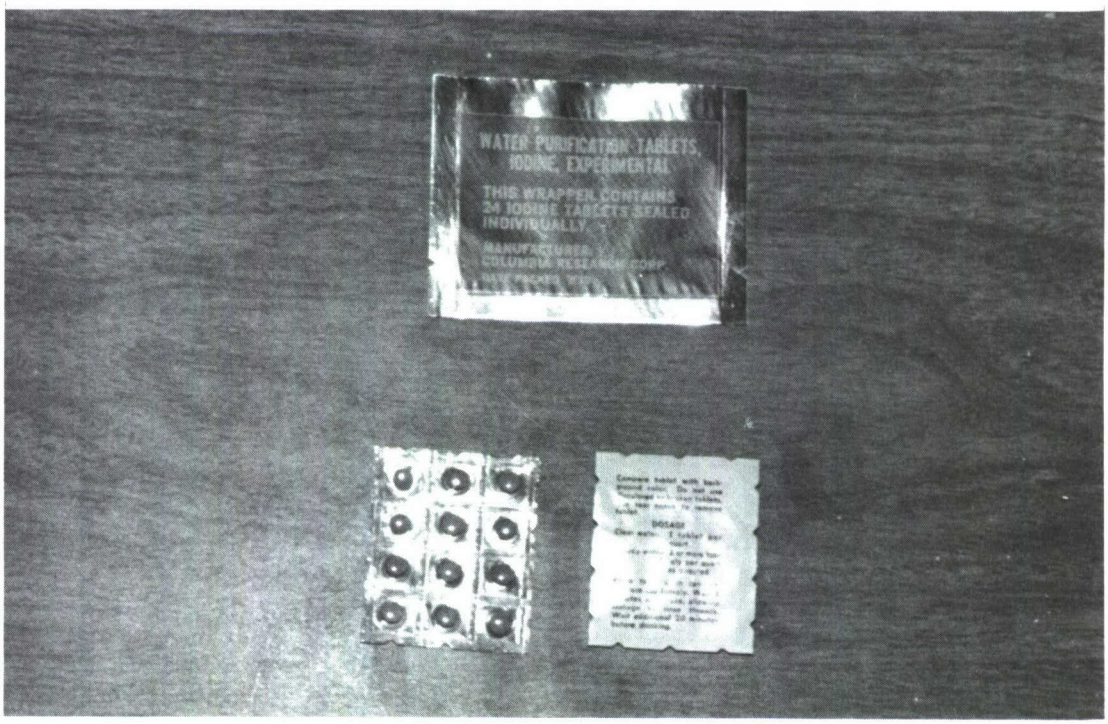


Figure 13. Blister Sheets and Pouch

Figure 14. Hand Filling Pouches

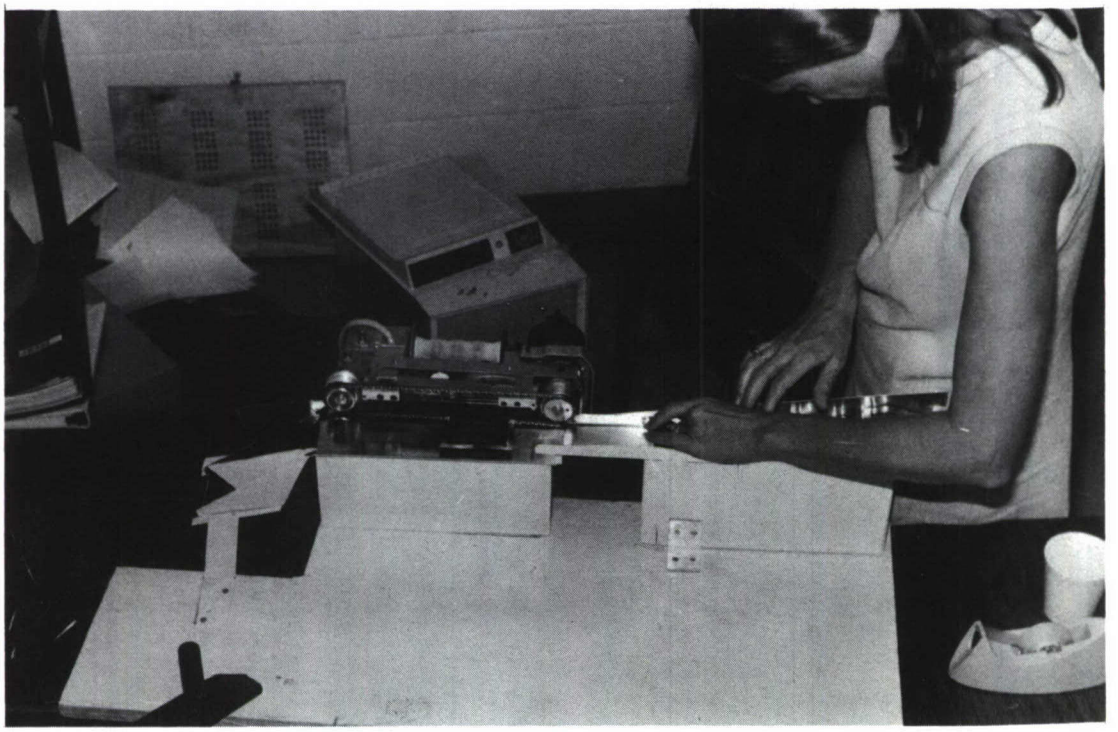


Figure 15. Sealing Filled Pouches

Figure 16. Filling Intermediate Boxes

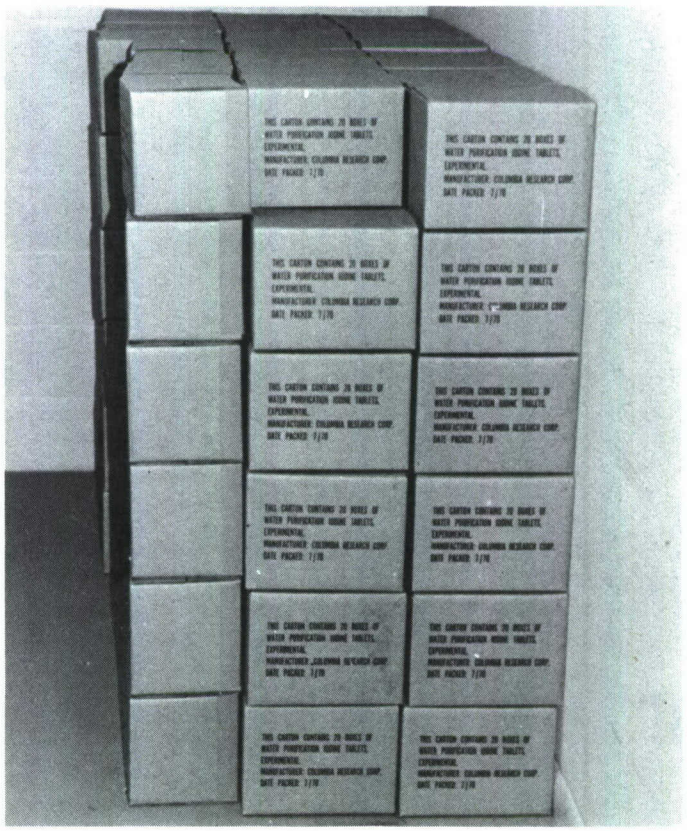


Figure 17. Filled Shipping Cartons

APPENDIX

SUMMARY

This appendix describes in detail the pilot production operation in making an experimental flexible package for the iodine water purification tablet. Fifty-five thousand (55,000) experimental flexible packages containing a total of over 1.3 million 115 mg iodine water purification tablets were produced. This appendix supplements information contained in Columbia Research Corporation Report No. 102-1, "A Blister Sheet and Pouch Overwrapper Package for the Iodine Water Purification Tablet."

Because the iodine tablet is highly corrosive and readily loses potency if exposed to moisture (i.e., high humidity), special materials and unique fabrication techniques were required. The developed package consists of a 3 3/8" x 2 5/8" pouch sealed over two transparent 2 1/8" x 1 3/4" blister sheets. Each blister sheet contains 12 individually heat sealed tablets and has, in addition, a pressure sensitive instruction label. The adhesive side of this label matches the gray color of a potent tablet and forms a background against which the tablets can be viewed through the transparent blister. Because discoloration of the tablet occurs when degraded, this background color match provides a rapid means for the user to eliminate those tablets which become impotent through intrusion of moisture or otherwise. Material used in the package consists of a laminated film of 0.5 mil Mylar - 0.35 mil aluminum foil - 3 mil polyolefin for the pouch; a fluorohalocarbon film of 5 mil Aclar 22A for both the front and back faces of the blister sheet; and a printed 2 mil cellulose acetate instruction label.

Because moisture degrades the iodine tablet, sealing of tablets in blister sheets and blister sheets in pouches are required to be performed in a low humidity environment with pre-dried packaging materials. Forming and sealing of Aclar film into blister sheets proved a difficult task because of its hypersensitivity to temperature variations in production machinery and the working environment. Also, variations among the different rolls of Aclar film themselves became a major obstacle. These factors contributed to a 30 percent scrap rate of the film during production.

Simulated environmental testing at elevated temperatures of a random sample of the pilot production run of packages has

indicated that they were packaged with the instruction (color match) labels containing a large amount of entrapped moisture. When tested at elevated temperature, this moisture was released within the pouch, creating a hot moist environment around the blister sheets, which, in time, caused deterioration of the tablets. This problem has subsequently been eliminated in laboratory test samples predrying the labels before application. Limited testing of these packages indicate that they should pass all storage and operational use requirements.

It is anticipated that minor development work in machine design would virtually eliminate Aclar Film waste, while a still further reduction in humidity during packaging would enable the package to pass all test specifications. Labels could also be fabricated of a less hygroscopic material than cellulose acetate film. The advantages of this package over the present 50-tablet bottle are:

Individually sealed tablets
Immediate field indication of tablet potency
More convenient shape (flat)
Reduced weight (60%)
More legible and informative instructions for use

The material cost for the package in production is estimated at $0.12 per package of 24 tablets, of which one-half represents the cost of the tablets themselves.

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INTRODUCTION

By contract amendment[1], the U. S. Army Land Warfare Laboratory (USALWL) requested Columbia Research Corporation (CRC) to prepare this Appendix to their final report[2] entitled "A Blister Sheet and Pouch Overwrapper Package for the Iodine Water Purification Tablet," CRC Report No. 102-1, of October 1970, in order to emphasize the pilot production operations during fabrication of the required fifty-five thousand packages called for under the original contract. The primary purpose of this Appendix is to provide sufficiently detailed information about the pilot production operations in order to permit USALWL to obtain additional quantities of the package, when desired, by competitive negotiation. Frequent reference is made herein to information and figures in the aforementioned report. Additional material contained in this Appendix includes a chronological listing and specific dates of the pilot production processes; a description of each production process, including detailed drawings; documentation of the basic materials used in the pilot production run; instructions for use of the particular machinery utilized in the pilot production run; a presentation and discussion of quality control tests; and an evaluation of the final package.

PILOT PRODUCTION SUMMARY

Figure A shows a flow chart of the sequence of pilot production processes and their dates of occurrence. The pilot production processes include, in chronological order, the following operations:

1. Forming, from rolls of 5 mil Aclar 22A film, twenty-two thousand (22,000)* sheets of blisters measuring 3½" x 13".

2. Shearing, from rolls of 5 mil Aclar 22A film, twenty-two thousand (22,000)* backing sheets measuring 2½" x 13".

3. Filling and sealing 1.3 million iodine tablets in the blister and backing sheets produced.

4. Applying twenty thousand (20,000)* labels to the sealed blister sheets.

5. Die cutting the labeled blister sheets to make in excess of one hundred ten thousand (110,000)* blister sheets containing twelve (12) tablets each.

6. Hand filling and sealing one hundred ten thousand (110,000) blister sheets into fifty-five thousand (55,000) pouches.

7. Erecting and filling five thousand five hundred (5,500) intermediate boxes, each containing ten (10) pouches.

8. Erecting, filling, and stapling two hundred fifty (250) shipping cartons, each containing twenty (20) intermediate boxes.

The relatively low production quantity did not justify use of highly automatic machinery which would have incurred high initial set-up expenses. Instead, many of the tasks were performed with machinery of limited capacity, or by hand.

*Excessive quantities were produced to account for production rejects.

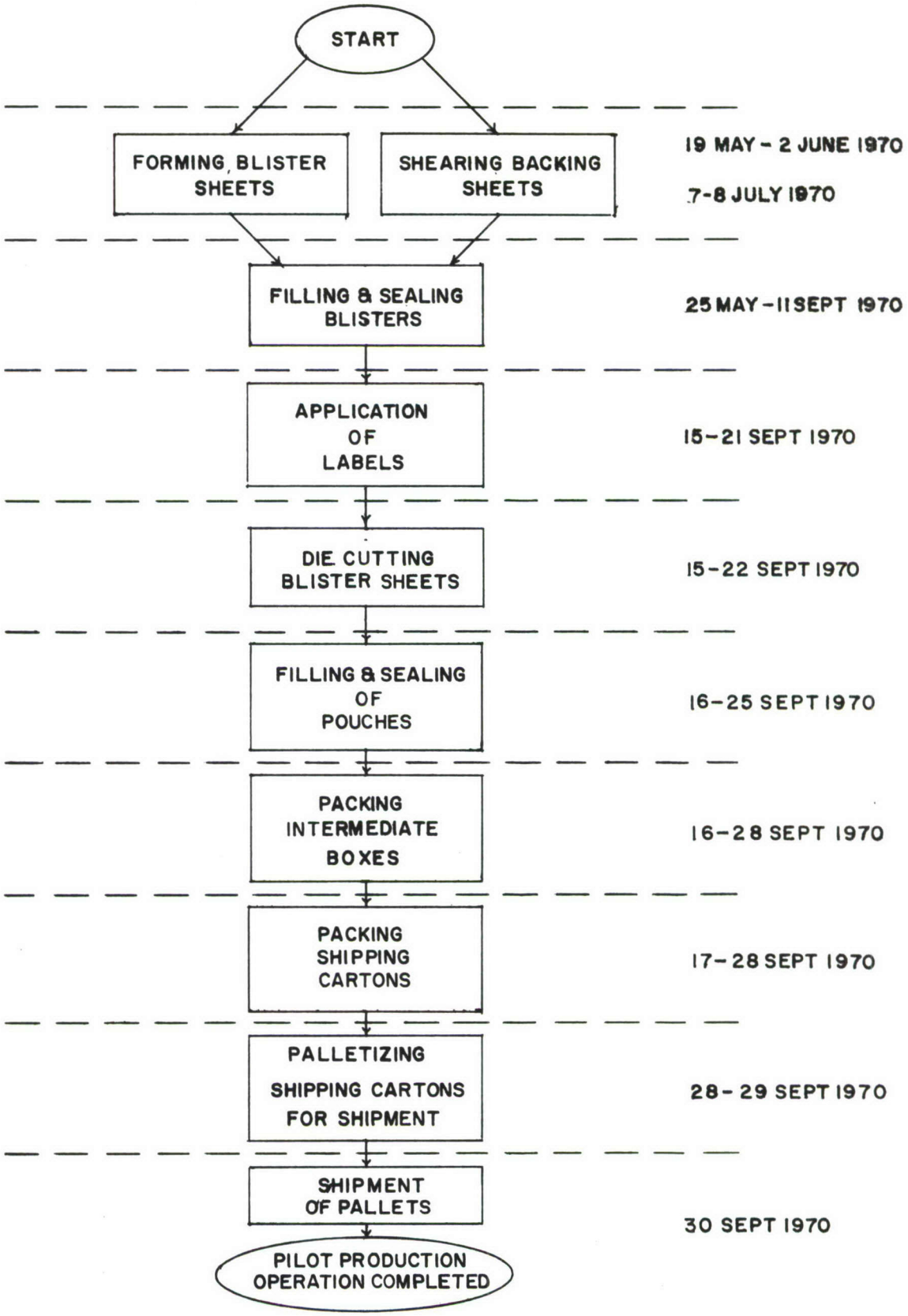


FIGURE A. FLOW CHART OF PILOT PRODUCTION MANUFACTURING PROCESSES AND DATES

The pilot production operation covered a 4½ month period from 19 May to 30 September 1970. It should be recognized that this was not the actual working time, but included also slack periods created by equipment failures and scheduling of operations. Referring again to Figure A, two time periods are associated with blister forming and shearing of backing sheets to account for receipt of material on two separate orders with a one month lapse in between. The three month period for filling and sealing blisters included only one month of actual operation, the other two months being down time because of production equipment failures. Had these failures not occurred, this production quantity of packages would have been completed in two months.

BLISTER FORMING

Machinery Description

Blisters from Aclar 22A film were formed on a Packaging Industries Sentinel Model JF-914 Blister Forming Machine. A male vacuum blister forming mold was designed and constructed for use with this machine to fabricate the blisters. Referring to the main report, Figure 4* shows the JF-914 in operation, Figure 6 shows a design drawing of one of the two identical sections of the forming mold, and Figure 7 shows a drawing of the 3½" x 13" blister sheet produced by the JF-914.

In operation, this machine automatically feeds a roll of film by engaging film edges with pins attached to a moving chain. The film is then passed under ceramic radiant heaters to reduce it to a plastic state. From here it proceeds into the water heated male vacuum mold where blister forming occurs. Following blister forming, the film moves to a trimmer, which removes the perforated edges, and thence to a shear, which cuts the roll into individual sheets of blisters.

Material Description

Aclar 22A film for blisters was supplied by the Fabricated Products Division of Allied Chemical Corporation in eight 15½-inch wide rolls with each roll comprised of between two and

*Numbered figures refer to the main report.
Lettered figures refer to this appendix.

four spliced lengths. Six rolls, each nominally 1,000 feet long and weighing 70 pounds, were received in May 1970, two additional rolls were received in July 1970, one approximately 1,000 feet long and the other approximately 500 feet long. Figures B and C are copies of the packing lists for these two orders. Figure C, the second order, was necessary to replace the unanticipated waste rate of film on the first order (Figure B).

Operations

The particular Sentinel Model JF-914 Blister Forming machine used on the pilot production was located in the facility of Clippette International, Inc. of Alexandria, Virginia. In operation, the JF-914 required a machine operator who monitored functioning of the machine and a production worker who stacked the sheared blister sheets (Figure 7) in cardboard boxes. During production, the JF-914 operated at the following machine settings.

Mold Temperature - 100 to 105°F
Blister Forming Period - 6 seconds
Ceramic Heaters - positioned 8 inches above film
- temperature control dials set at 70 (Temp. relation unknown)
Edge Trimmers - reduce roll width to 13 3/32 inches
Index Length - 3 1/2 inches

FABRICATED PRODUCTS DIVISION
ALLIED CHEMICAL CORPORATION
P. O. BOX 697
POTTSVILLE, PENNA. 17901

Sheet No. 1 of 1

Consignee Order No. 430
Fanfold No. 85485
Shipped To COLUMBIA RESEARCH CORP.
CLOPPER RD.
GAITHERSBURG, MD.

Att. MR. D. BROWN

Date
Shipped Via
Packed By
Checked By A.H.

Net Weight 430.0

FILM PACKING LIST

TYPE	GAUGE	ROLL NUMBER	LENGTH	GROSS	TARE	NET	WIDTH
22A	5 MIL	G705-029-3-3	1035	156.0	10.0	74.0	15¼
"	"	G-705-029-3-1	1000	—		72.0	"
"	"	G705027-3-1	945	145.0	10.0	68.0	"
"	"	G705027-3-3	945	—	—	67.0	"
"	"	G705027-3-2	980	159.0	10.0	70.0	"
"	"	G611035-3-2-1	1070	—	—	79.0	"
		3-CARTONS			30.0		
		6-ROLLS		460.0		430.0	

G-304 Rev.

FIGURE B PACKING LIST FOR BLISTER SHEET FILM OBTAINED MAY 1970

FABRICATED PRODUCTS DIVISION
ALLIED CHEMICAL CORPORATION
P. O. BOX 697
POTTSVILLE, PENNA. 17901

Sheet No. 1 of 1

Consignee Order No. 430
Date
Fanfold No. 85759
Shipped Via
Shipped To COLUMBIA RESEARCH CORP.
CLOPPER RD.
GAITHERSBURG, MD.
ATTN: MR. D. BROWN
Packed By
Checked By A.H.
Att.
Net Weight 101.0

FILM PACKING LIST

TYPE	GAUGE	ROLL NUMBER	LENGTH	GROSS	TARE	NET	WIDTH
22A	5 MIL	G-611035-3-1-1	960	111.0	10.0	66.0	15"
"	"	G-611038-3-8	490	—	—	35.0	"
		1-CARTON		111.0	10.0		
		2-ROLLS				101.0	

G-304 Rev.

FIGURE C PACKING LIST FOR BLISTER SHEET FILM OBTAINED JULY 1970

During forming it was noted that malformed blisters resulted from small variations in machine operating parameters. For instance, if the ceramic radiant heaters become too hot, material foldover occurred in the mold during drawdown; if temperatures become too cold, incomplete blister forming resulted. Similarly, a mold temperature slightly hot caused inverted blisters while a temperature slightly cold caused incomplete blister forming. Daily temperature fluctuations within the plant were also a factor that continually necessitated minor machine adjustment to produce good blisters. In addition, variations in the Aclar film itself required frequent machine adjustments during forming. These film variations are discussed below.

The six rolls of film obtained on the order listed on Figure B were formed over six working days between the period of 19 May and 2 June 1970. Variations in the forming characteristics were noticed among the approximate twenty spliced lengths of this order. These variations required minor readjustments, during machine operation, of the forming mold temperature setting and of the ceramic heater positions and temperatures. Because the JF-914 responded slowly to these adjustments as it was operating, approximately 30 percent of this film was lost in non-reusable scrap in the form of malformed blisters. Inspection of the film showed that one of the spliced lengths measured only

3.5 mils in thickness while Roll No. G-705029-3-1 (Figure B) contained a large amount of embedded grit and other foreign matter. It was observed also that these six rolls in film were less flexible in nature than that film listed in Figure C as well as that film comprising a 200-foot roll obtained earlier during the development of blister forming processes.

The two rolls of film listed in Figure C were obtained to replace scrap incurred during the forming of the Figure B order. These rolls were formed into sheets on the 7th and 8th of July 1970. Blister forming from these rolls was much easier, with minimal loss from malformed blisters.

BACKING SHEETS

Machinery Description

A second Sentinel Model JF-914 was utilized as an automatic shear to cut rolls of 5 mil Aclar 22A into backing sheets measuring 2 1/2" x 13". To function only as an automatic shear, the forming equipment of this machine was deactivated. Deactivation procedures included turning off the ceramic heaters and disengaging the forming mold. Otherwise, this machine fed rolls of film through the machine in the same manner as in blister forming with the edge trimmer and shear cutting the roll stock into the aforementioned size sheets.

Material Description

Backing sheets were cut from three rolls of 5 mil Aclar 22A film, 14 inches wide which had been corona etched on the outside. Corona etching is a process of electrostatically roughening the surface of a film to give it better adhesive characteristics (e.g., in this case for pressure sensitive labels). The film was supplied by the Fabricated Products Division of Allied Chemical Corporation. Figure D shows the packing list of this material, which was shipped with the Figure B blister film list. Two of the rolls measured approximately 2000 feet in length, while the third roll measured 830 feet. Each of the three rolls contained between two and three splices.

FABRICATED PRODUCTS DIVISION
ALLIED CHEMICAL CORPORATION
P. O. BOX 697
POTTSVILLE, PENNA. 17901

Sheet No. 1 of 1

Consignee Order No. 300
Fanfold No. 85484
Shipped To COLUMBIA RESEARCH CO.
CLOPPER AVE.
GAITHERSBURG, MD.
Att. MR. D. BROWN

Date 5-8-70
Shipped Via
Packed By
Checked By AH. JLS
Net Weight 316.0#

FILM PACKING LIST

TYPE	GAUGE	ROLL NUMBER	LENGTH	GROSS	TARE	NET	WIDTH
22A	5MIL	G502433-3-2-1	830	66.0	11.0	55.0	14"
"	"	G705026-3-2-2	2030	143.0	"	132.0	"
"	"	G705030-3-1	1970	140.0	"	129.0	"
	1-PALLET			50.0			
	2-CARTONS				33.0		
	3-ROLLS			399.0#		316.0#	
	TREATED OUTSIDE						

Material Received
Date By
Account No. 5/29/70 103
Check No.
Date Paid
Posting Reference

G-304 Rev.

FIGURE D PACKING LIST FOR BACKING SHEET FILM

Operations

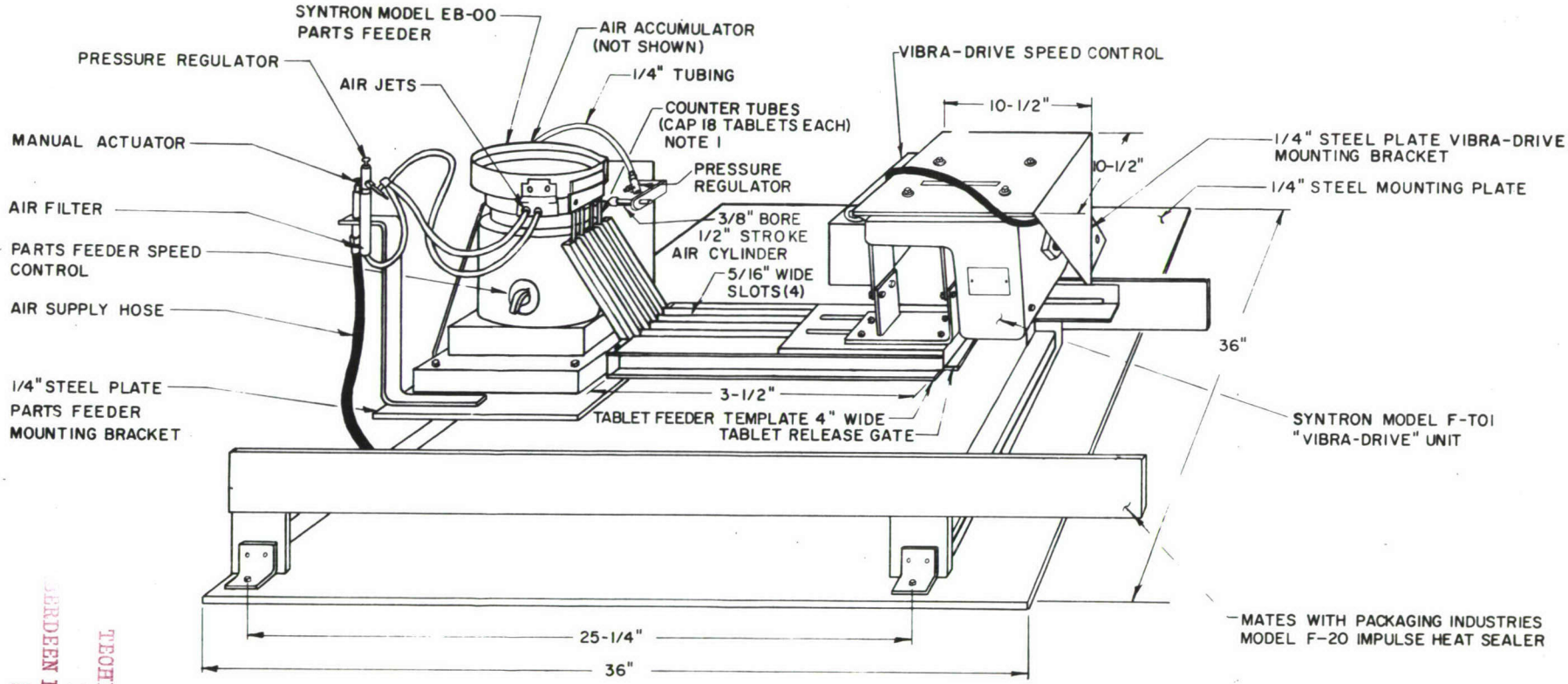
The Sentinel Model JF-914 used for shearing backing sheets was located adjacent to its twin unit used in forming blisters at the Clippette International plant in Alexandria, Virginia. Operation of the machine required a machine operator who monitored functioning of the machine and a production worker who caught each sheet when sheared. Because the corona etching was not visually discernible, it was important that the production worker stack the cut sheets with etched faces in a common direction. The two 2,000 foot rolls were cut into sheets and stacked in cardboard boxes on the two days of 19 and 20 May 1970. Because of the uncertainty at that time of receiving the replacement blister sheet film listed in Figure C, the third roll (830 foot length) was not sheared until the 7th of July. Waste was minimal during the shearing of backing sheets, being confined to trimming off of the perforated edge of the roll, and discarding of the few sheets which contained splices, or which were miscut by an occasional hang-up in the roll feed.

FILLING AND SEALING BLISTER SHEETS

Machinery Description

A specially designed automatic tablet filler was used to fill blister sheets, which were then sealed using a Packaging Industries Sentinel Model F-20 Impulse Heat Sealer. This equipment uses a two-part sealing tray to accomplish sealing of the blister and backing sheets from both sides. For each cycle of operation, this combination of equipment filled and heat sealed 72 iodine tablets between the 3½" x 13" blister sheets and 2½" x 13" backing sheets. (Figure 10 shows a photograph of the complete system.) The lower half of the sealing tray holds the blister sheets, and slides manually along rails between the tablet filler and heat sealer. When the tray is slid to the tablet filler, all 72 tablets drop simultaneously into the blisters. At a station midway between the filler and sealer, a backing sheet is hand applied over the filled blisters. The tray is then shuttled into the heat sealer where the backing and blister sheets receive a heat seal gridwork that isolates tablets from one another. This operation is described in detail below.

Figure E shows a detailed sketch of the automatic tablet filler designed and fabricated by Columbia Research Corporation. The operational sequence for filling begins with loading iodine



NOTE 1 COUNTER TUBES HINGED TO FEEDER BOWL

FIGURE E AUTOMATIC TABLET FILLER

tablets from 1,000-tablet bottles into the Syntron Model EB-00 Parts Feeder. Vibration action propels tablets along a spiral ridge within the bowl into four counting tubes of 18-tablet capacity each. Once all tubes are filled (i.e., all 72 tablets), the remaining tablets fall back into the bowl and continue to circulate. Slots cut in the bowl wall allow the unwanted dust and broken tablets to escape.

When activated, a pneumatic piston connected to the hinged counting tubes swings these tubes clear of a gate to eject tablets onto an aluminum four-channeled template. At the same time, an air jet located in the bowl downstream of the counting tubes blows circulating tablets back into the bowl before they can reach the now opened filling tubes. When the piston is deactivated, the tubes return to their former position, the air cuts off, and another load of tablets refills the tubes.

The four-channel template is bolted to an overhead mounted Syntron F-T01 Vibra Drive, which, like the parts feeder, uses vibration action to propel tablets. Spaced along the bottom of each channel are eighteen 0.30-inch diameter holes arranged in a pattern that matches the blisters in the blister sheet. The holes are closed off or opened up by a spring loaded sliding gate mounted beneath the template. Following ejection from

the counting tubes, the tablets are vibrated into the closed off holes along each channel. When the sealing tray is slid beneath the template (Figure 9, main report), it triggers the gate causing all tablets to simultaneously drop into the blisters which are aligned in the tray underneath the template. When the tray is withdrawn, the gate closes, and the template is ready for another load of tablets from the counting tubes.

The two-part sealing unit comprised of two trays was designed to make heat seals from both sides of the blister sheets when incorporated with the Packaging Industries Model F-20 Impulse Heat Sealer. The lower tray supports the blister sheets and is shuttled by hand along rails between the F-20 and the tablet filler while the upper tray mounts in the F-20 on the pneumatically actuated overhead plate.

The rectangular tray bases are constructed from 5/8" thick phenolic. The upper one measures 12" x 22½", and the lower one measures 14½" x 22½". Sealing elements are glued to the trays and constructed from a 4-mil thick nickle-iron alloy. This alloy is photo-etched to make seals 3/32" wide and arranged in a pattern to make multiple parallel seals between and along the outside edges of the blisters. Power for the sealing elements is supplied at a 40-volt potential from the F-20 through the electrical contacts and wires incorporated in the tray.

A 5-mil teflon pressure sensitive sheet is applied over the elements to prevent them from sticking to the blister sheets.

The sealing elements of both trays are arranged to make longitudinal seals on one side of the trays and transverse seals on the other side. Therefore, two sealing operations are required to make a gridwork of seals around the blisters. In operation, longitudinal seals are made first, followed by movement of the sheet to the second station on the lower tray where the transverse seals are made.

When the lower tray with unsealed blister sheets is shuttled into the F-20, the pneumatically actuated upper tray is forced down under pressure to the lower tray, thus sandwiching the blister sheets in between. Upon application of pressure, a switch activates power to the sealing elements for a fixed time interval which is set by an adjustable timer. The trays continue to be held together following the cutoff of power to permit seal cooling under pressure for a specific time interval which is set by a second timer. Following this operation, the top tray is automatically retracted, thus permitting withdrawal of the lower tray which contains sealed blisters.

Filling and Sealing Operations

A week prior to commencing blister filling and sealing operations, the blister and backing sheets were stored with

the bottles of iodine tablets in the low humidity room containing the filling and sealing system. This was done to remove excess moisture from these sheets, which would degrade the tablets if sealed in the blisters. Humidity readings taken daily with a sling psychrometer showed a relative humidity level of 35% at 72°F. In absolute humidity units, during filling and sealing operations, this value corresponded to 6.00 grams of water per cubic meter of air (6.00 gr/m^3) which was within the specification requirement of 7.59 gr/m^3 (i.e. 30% RH at 80°F).

A low humidity environment, in addition to being necessary for the maintenance of tablet potency, was also necessary to keep the automatic tablet filler from fouling. Attempts to run the tablet filler in high humidity caused tablet deposit build-up in the counting tubes and template holes, thus reducing clearances to a point where they would not accommodate tablets. When this occurred, a thorough cleaning of holes and tubes with a wire gunbrush was required to restore the filler to an operating condition. However, cleaning of deposits was unnecessary if the air was kept within the low humidity specifications.

The filling and sealing task took 26 working days using both a machine operator and a production worker. Because of wasted time caused by burnouts of sealing tray elements, this operation

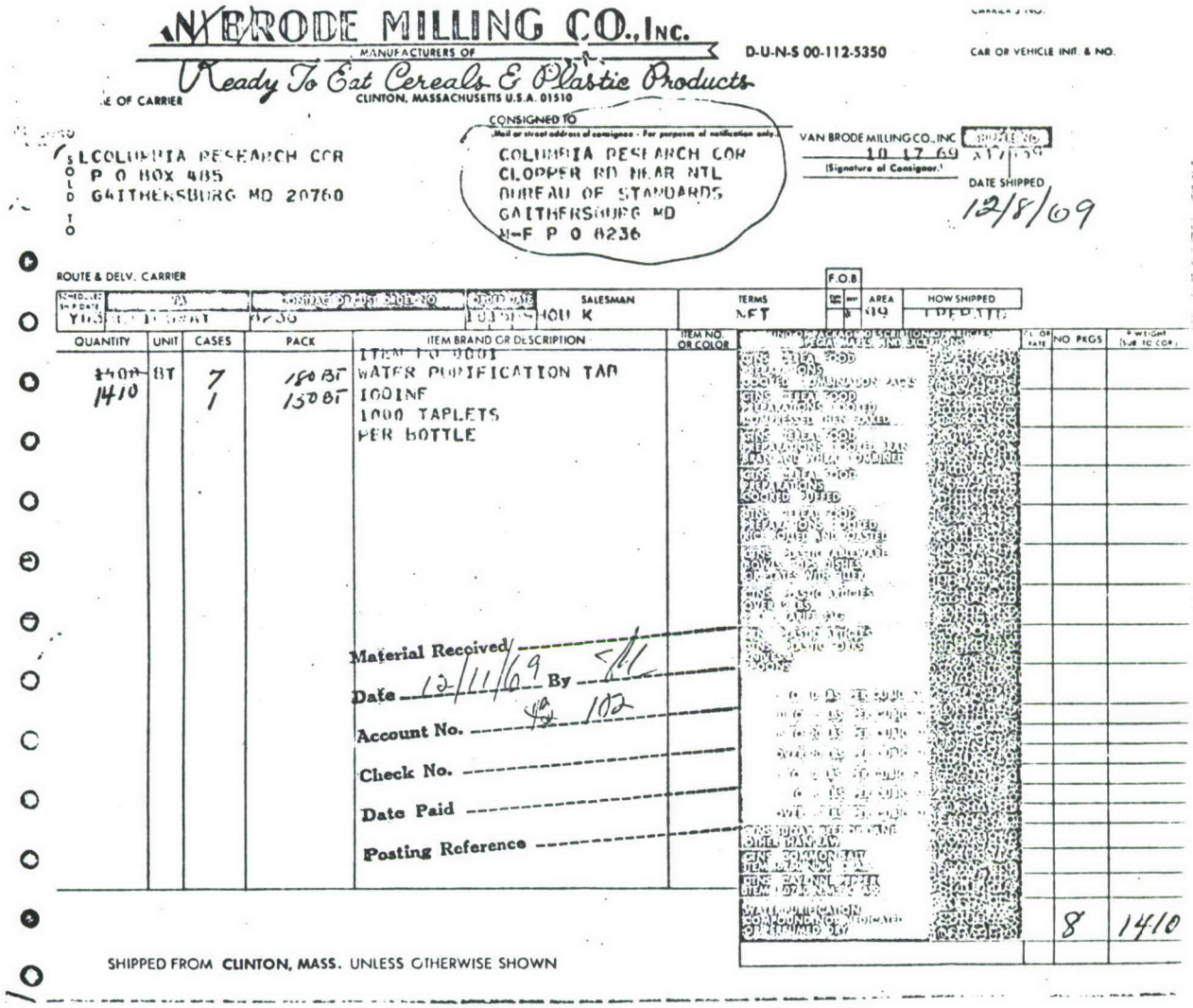
was spread over a 3½-month period between 25 May and 11 September of 1970. Considerable additional expense was accrued because of sealing tray burnouts. These expenses were manifested by unproductive labor costs, costs for tray repairs, and the costs for purchase of a second backup sealing tray. It is estimated that such expenses amounted to approximately five thousand dollars ($5,000).

When the sealing and tablet filling machinery was being operated smoothly by experienced personnel, between 50 and 60 thousand tablets were filled and sealed daily. This quantity of tablets corresponded to between four and five thousand die cut blister sheets of one dozen tablets each. The rate of production was limited by a long sealing cycle of approximately ten seconds. During filling operations, it was noted that approximately 10 percent of the iodine tablets in the sealed one-thousand tablet bottles contained tablets with yellow spots. Although an attempt was made to remove these tablets during the filling operations, the spots often were visible from one side only; and, consequently, a large number were loaded and sealed in blisters before detection. Sealed blister sheets were then stored in cardboard boxes which were identified according to packaging date. A ½ percent sample quantity after each day's run was set aside for quality control testing.

Iodine Tablet Storage History

The iodine water purification tablets used to fill blister sheets were supplied in 1,000-tablet bottles by the Van Brode Milling Company, Incorporated, the sole manufacturer of the iodine tablet. Figure F shows the packing list for the 1,410 bottles (i.e., 1.41 million tablets) shipped in eight cases. These tablets were of Lot No. 8236 manufactured in December 1969, and were shipped that same month to Columbia Research. Unfortunately, these tablets were ordered from Van Brode by Columbia Research Corporation without the requirement that they conform to the military specification for manufacture of the water purification tablet (MIL-W-283F). Because of this oversight, the quality of these tables was probably not on a par with those ordered by the military. Twelve thousand 50-tablet bottles, which were packed in intermediate boxes, were provided in April 1970 by USALWL. These tablets were of Lot No. 0618-521, manufactured by Van Brode in November 1969 and allegedly were produced under quality controls which met the above military specification.

Because blister filling and sealing did not start until May 1970, the 1,000-tablet bottles were stored by Columbia Research at their production facility in Gaithersburg, Maryland from December until May 1970. No heating or air conditioning existed in this area, and they were thus subjected, for all practical purposes, to the daily and seasonal variations in



VAN BRODE MILLING CO., INC.
MANUFACTURERS OF
Ready To Eat Cereals & Plastic Products
CLINTON, MASSACHUSETTS U.S.A. 01510
D-U-N-S 00-112-5350

CONSIGNED TO
COLUMBIA RESEARCH COR
CLOPPER RD NEAR NTL
BUREAU OF STANDARDS
GAITHERSBURG MD
N-F P O 0236

SOLD TO
COLUMBIA RESEARCH COR
P O BOX 485
GAITHERSBURG MD 20760

VAN BRODE MILLING CO., INC
10 17 69
DATE SHIPPED
12/8/69

QUANTITY	UNIT	CASES	PACK	ITEM BRAND OR DESCRIPTION	ITEM NO. OR COLOR	NO PKGS
1410	BT	7	180 BT	WATER PURIFICATION TAB		
		1	150 BT	IODINE		
				1000 TAPLETS		
				PER BOTTLE		
						8

Material Received
Date 12/11/69 By
Account No. 102
Check No.
Date Paid
Posting Reference

SHIPPED FROM CLINTON, MASS. UNLESS OTHERWISE SHOWN

FIGURE F PACKING LIST FOR IODINE TABLETS

temperatures and humidity. In May 1970 these tablets were transported to the aforementioned controlled low humidity room at Alexandria, Virginia.

The 50-tablet bottles were stored from April until September 1970 in the same production working area at Columbia Research. In September 1970 these bottles were transferred from their shipping cartons to intermediate boxes which were then cartoned and palletized. Shipment of the packages of iodine tablets to USALWL and the Natick Laboratories was made on 30 September 1970.

BLISTER SHEET LABELS

Materials and Manufacturing Processes

The labels containing the use instructions and gray background color match were manufactured by the Allen Hollander Corporation. Twenty thousand of these labels were supplied in individual sheets measuring 2 1/2" x 12 3/4", with each sheet containing six sets of use instructions. Figure 8 shows a photograph of the label. Six sets of use instructions are printed on each label. Each set of instructions are printed within a 1 1/8" x 1 9/16" area and were spaced to fall over the center of 4 x 3 groups of tablets which comprised the individual 1 3/4" x 2 1/8" blister sheets after die cutting.

The label stock used in the label was comprised of transparent 2 mil cellulose acetate film containing an XS 232 acrylic adhesive on its pressure sensitive face. This stock was manufactured by the Fasson Corporation and supplied in sheets measuring 13" x 13 1/2".

The transparent label stock sheets were fabricated into labels by printing on a standard Heidelberg Eastern Letterpress with a series of different inks supplied by the Sinclair and Valentine Corporation. Six printing operations using five separate inks were required. These operations, listed in sequence along with identification numbers of inks, were:

2 coats of tablet match gray (7-1-70S)
1 coat blue-white (PMS-IN50)
1 coat silver (PMS-IN1)
1 coat blue-white (PMS-IN50)
Black printing of use instructions (PMS-IN47)

The inking processes were such that two gray coats were needed to produce uniform gray coverage. The first coat of blue-white was required to preserve the matching gray color (the gray ink was matched for the blue-white coating). A silver coat was added to give opacity to the label. The second blue-white coating provided the contrasting background for the black printing.

Thirty sets of use instructions were printed on the 13" x 13½" sheets. Following the inkings, the final operation was to slit the sheets into the five smaller sheets, each measuring 2½" x 12 3/4" as shown in Figure 8. When the label was applied to the back of the blister sheet, the matching potent tablet gray color would show through the transparent label and blister films and thus form the background color match, while the use instructions could be read on the reverse side of the label.

Application Procedures

The technique of applying labels by hand was simply to strip the label of its protective backing which was then laid adhesive side up on a flat surface. A filled blister sheet, backing face down, was then aligned by eye and dropped onto the

label. This was followed by a single sweep of the hand across the label surface to assure good adhesion. Labels were applied to the 20,000 uncut blister sheets over a 7-day period between 15 and 21 September 1970. Once personnel became proficient in this operation, two production workers could apply between 2,500 to 3,000 labels daily.

DIE CUTTING BLISTER SHEETS

Equipment Description

A die cutter was designed by the Diematic Corporation to cut the sealed and labeled blister sheets into six smaller sheets of the specified size of 1 3/4" x 2 1/8", with each sheet containing one dozen tablets. Figure 11 shows a photograph of the cutting die. The cutting blades are made from SAE 1095 steel rule and mounted in a plywood and steel base. The blades are formed to cut tear notches 0.40" deep opposite each outside tablet.

The cutting die was used with the USM Hytronic Die Cutting Machine shown in Figure 12, where the cutting operation is being performed. In operation, the uncut sheets are placed with the blisters face down in the die. The head of the die cutting machine, having a rubber composition pad, is then swung into position over the die and hydraulically activated downward to apply the required pressure for cutting each large sheet into the six smaller sheets of the specified size.

Figure G shows the pertinent dimensions of the blister sheet after die cutting. A photograph showing the front and back faces of the blister sheet in relation to the pouch over-wrapper is shown in Figure 13 of the main report.

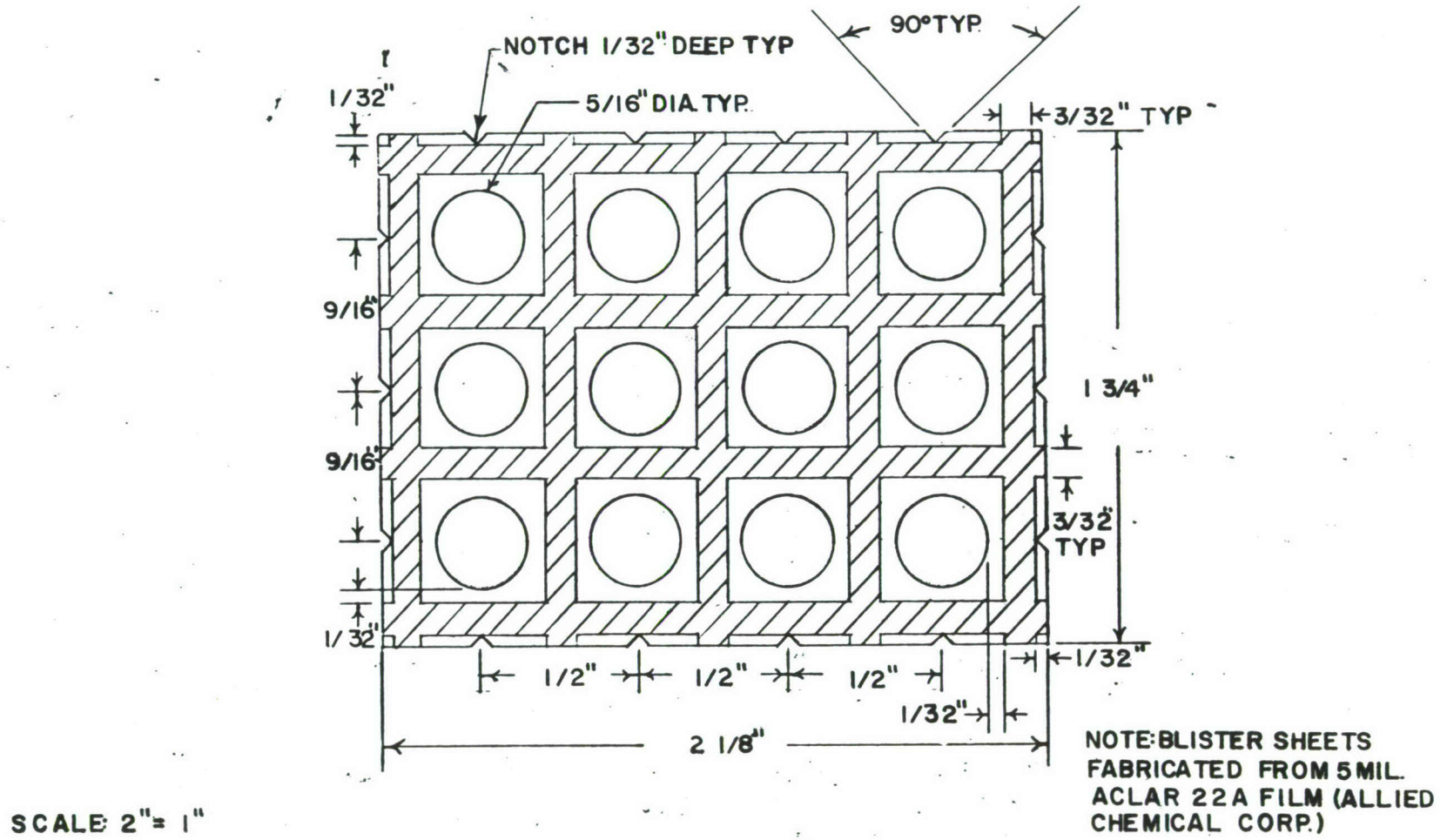


FIGURE G. IODINE WATER PURIFICATION TABLET BLISTER SHEET

Die Cutting Operations

The die cutting of the 20,000 labeled, filled, and sealed blister sheets to make 120,000 notched sheets of one dozen tablets each, took eight days, using a machine operator to operate the press and one production worker to separate the trimmed scrap from the blister sheets. Die cutting operations proceeded smoothly with the exception of an occasional sheet which was not properly seated in the die. When this occurred, the applied pressure from the die cutter head crushed all tablets. Crushing was most frequent with wrinkled sheets, which did not lie flat in the cutting die. Approximately 1½ percent of the blisters were crushed during the die cutting process.

POUCHING BLISTER SHEETS

Pouch Design

The Continental Can Corporation supplied the fifty-five thousand (55,000) individual pouches. These were fabricated from a laminated film of 0.5 mil Mylar-0.35 mil aluminum foil-3.0 mil C79 polyolefin. In the fabrication of this film, a polyurethane adhesive, applied at the rate of 0.6 pounds per 1,000 square feet between substrates, bonds the film together. The film then passes through an oven kept at a temperature between 145° and 180°F, and from there it is cured for several days at 100°F.

A photograph of the pouch as fabricated, along with two blister sheets, is shown in Figure 13. The pouch measures 2 5/8" x 3 3/8" and has 1/4" wide heat seals along three of its edges. The fourth edge is left unsealed for hand filling of two nested blister sheets. Tear notches are provided along edges of the pouch to facilitate its opening when sealed. Because of the relatively low quantity order, flexographic printing methods were used to color and label the pouches externally on the Mylar. To prevent ink removal during sealing, edges of the pouches were left uncolored. In large production quantities, which would justify the added expense, the Mylar would be reverse printed on its inside face adjoining the aluminum substrate

to eliminate the problem of ink removal, thus permitting total coloring.

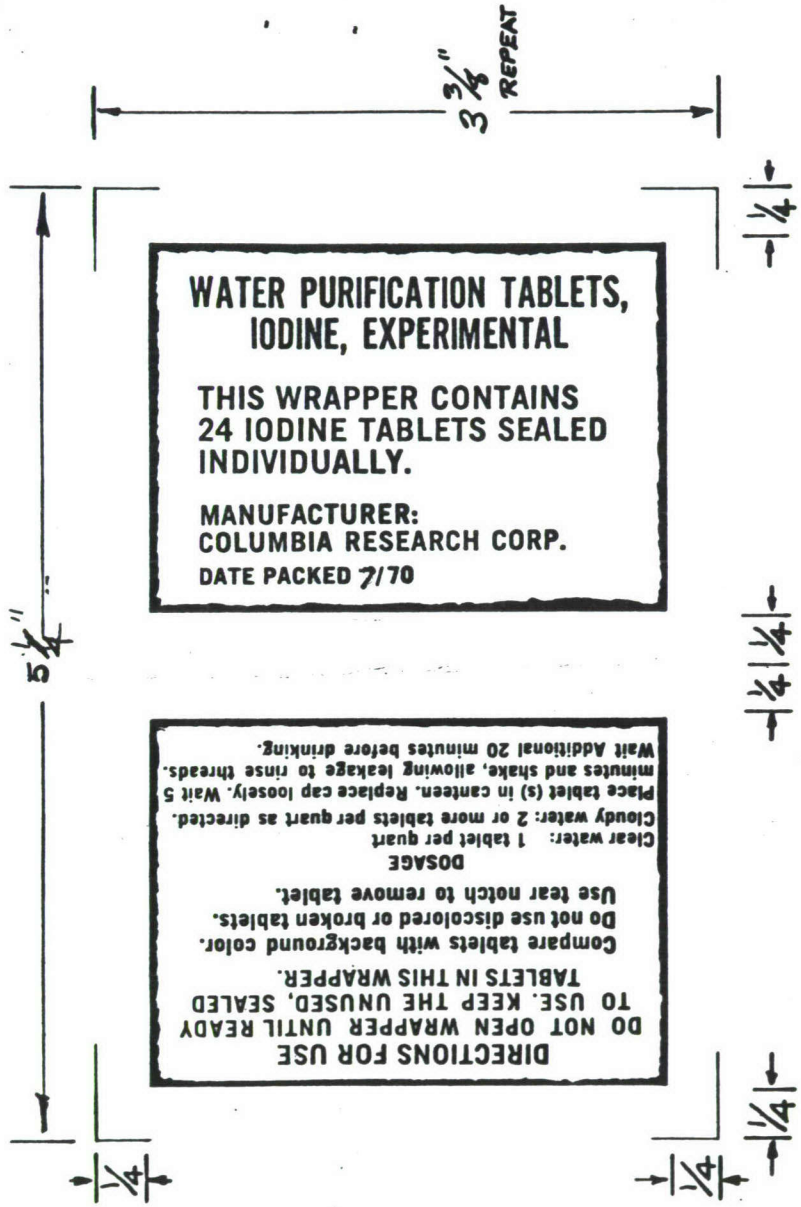
The pouch film stock was printed with the contract specified information as shown in Figure H. This figure also shows the dimensions of the finished pouch in addition to the serrated fourth seal made at Columbia Research after hand filling. This operation is described below.

Sealing Equipment

Each pouch was filled with two blister sheets, the blisters facing each other and nested. Figure 14 shows this operation being performed.

The filled pouches were heat sealed by using a Doughboy Model HS-B heat sealer, modified at Columbia Research with a pouch sealer guide for this particular operation. Figure I shows a sketch of this sealer mated to the pouch guide. A photograph of the sealer system in production is shown in Figure 15.

In operation, the sealer engages the open lips of the pouch between two motor driven chains moving at 200 inches per minute. While the engaged pouch is moved by the chain drive, heater bars arranged parallel to the chains are set at 450^{o}F to heat the lips of the pouch. At the far end of the sealer, the pouch lips are pressed together under pressure by two serrated rollers to form the seal. From that point, the pouches are ejected from



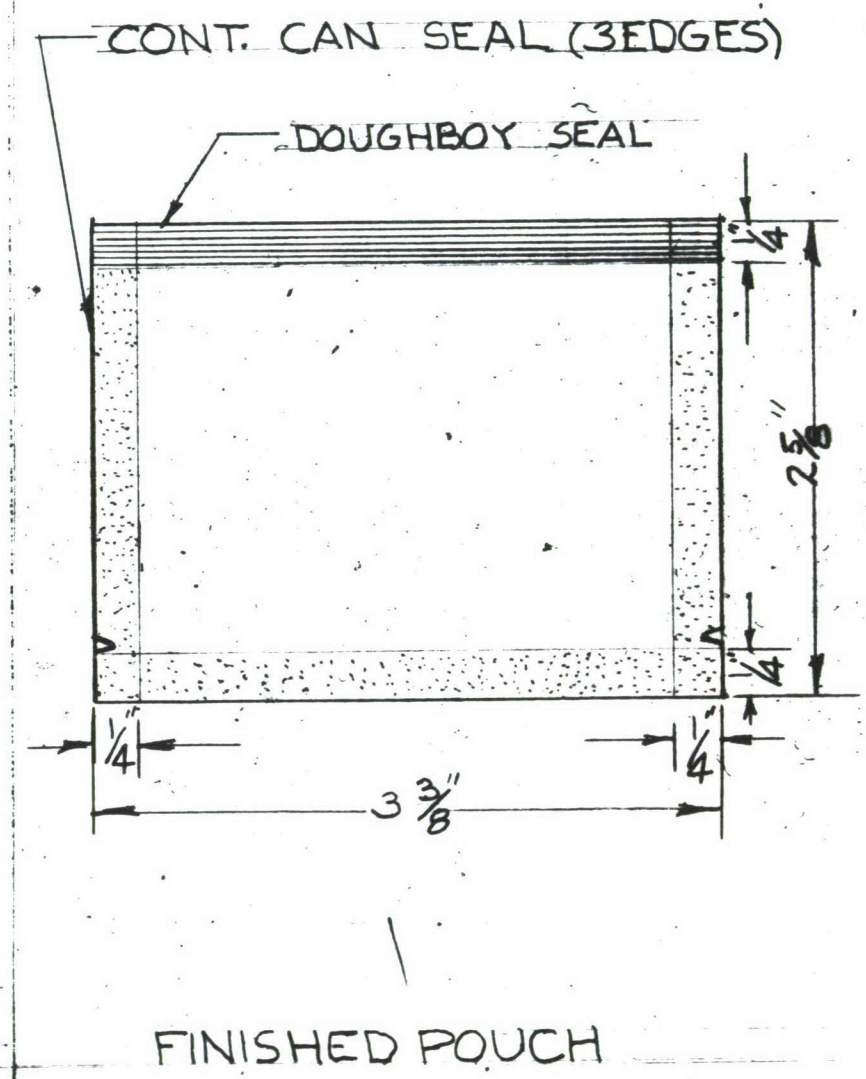
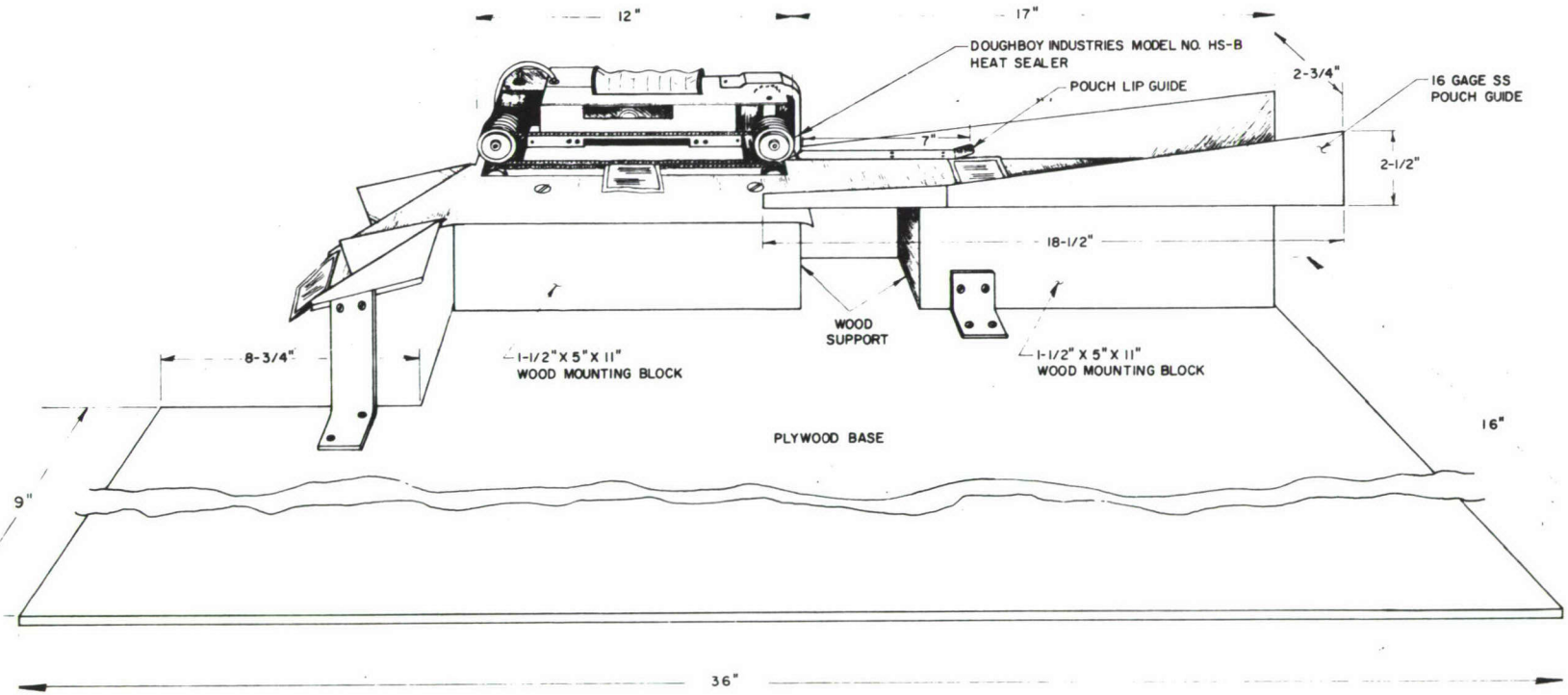


FIGURE H. POUCH OVERWRAPPER



POUCH SEALER

FIGURE I POUCH SEALER

the sealer and collected in a large cardboard box.

Pouching Operations

The 110,000 blister sheets were handloaded and sealed at the Columbia Research Corporation facility in a room maintained at 75°F and 35% RH. This work was performed by four production workers over a 10-day period between 16 and 25 September 1970. Blister sheets were visually inspected for tablet discoloration before being packed in pouches, and any sheet containing a discolored tablet was rejected. Approximately five percent of the blister sheets were rejected in this manner. During production, a three-man force, hand loading pouches, could maintain pace with an operator feeding the filled pouches through the Doughboy HS-B Heat Sealer.

INTERMEDIATE BOXES AND SHIPPING CARTONS

Intermediate boxes and shipping cartons were supplied by L. Gordon and Son, Inc. The 5,400 intermediate boxes were of paperboard and measured 3 1/2" x 3 1/2" x 2". Each box was designed to contain ten filled pouches and two 50-tablet bottles. A paperboard insert within this box gave a snug fit to the pouches and bottles.

The 250 shipping cartons were fabricated from a weather resistant, single wall, corrugated fiberboard of type V3C conforming to Federal Specification No. PPP-B-636E. These cartons measured 10 3/4" x 7 1/2" x 7 3/4" and held 20 intermediate boxes. A heavy duty manually operated stapler was used to erect and seal the shipping cartons.

Packing of intermediate boxes and shipping cartons was integrated with the operation of sealing the blister sheets in pouches at Columbia Research between 16 and 25 September 1970. Approximately four man-days were required to hand pack the 55,000 pouches and the 11,000, 50-tablet bottles into the intermediate boxes and the intermediate boxes into shipping cartons.

QUALITY CONTROL TESTS

Test Description

A one-half percent sample (550 units) of the 110,000 blister sheets produced in lots of 2,000 (10 units) were drawn for quality control testing purposes. Each sample of 10 sheets per lot were handled as follows:

1. One sheet from each 10 was subjected to immediate titration.
2. One sheet from each 10 was subjected to a humidity test for five days at 115°F and 100 percent RH, followed by titration to determine quantity of the iodine content.
3. Three sheets from each 10 were subjected to a vacuum leakage test.
4. Three sheets from each 10 were subjected to visual examination, polarimeter check, random measurement, and other manual tests.
5. The remaining two sheets were held in reserve for additional tests, if required, or for confirmation tests should the titrations indicate marginal iodine activity.

In addition to the foregoing, 240 pouches were drawn as a sample, each of which was subjected to detailed visual examination. A random 10 percent was then subjected to a vacuum leakage test.

Procedures for performing tests were outlined in the main report.

Test Data

Tables 1, 2, and 3 present, respectively, the results of these individual samples which were immediately titrated after packaging, those which were titrated after being subjected to 115°F @ 100 percent RH for 5 days and those which were subjected to vacuum leakage testing. For the titration tests the mean value of the titratable iodine $\bar{I}$ was calculated according to the relation

$$\bar{I} = \frac{\sum I_s}{N}$$

where I_s is the titratable iodine for each sample and N is the number of samples.

Assuming a Gaussian or normal distribution, an estimate of the standard deviation S was calculated according to

$$S = \left(\frac{\sum (I_s - \bar{I})^2}{N - 1} \right)^{\frac{1}{2}}$$

In vacuum leakage tests, each sample size consisted of 20 sheets. A failure was indicated by a discoloration of the tablet caused by intrusion of water through a faulty seal. Failures among samples of 20 sheets each are tabulated according to the number and percentage of blister sheets which failed (where one or more discolored tablets were observed) and according to the number and percentage of blister failures. The number and percentage of failures by considering all samples as a single group are also given.

TABLE 1 - TITRATABLE IODINE FOR SAMPLES TITRATED IMMEDIATELY AFTER PACKAGING

Sample No.	I (mg)	Sample No.	I (mg)
1 (12 tablets)	8.36	17	8.36
2	8.36	18	7.89
3	8.31	19	8.36
4	8.10	20	8.21
5	8.15	21	8.05
6	8.31	22	8.63
7	8.05	23	8.47
8	8.31	24	8.47
9	8.15	25	8.26
10	8.21	26	8.31
11	8.15	27	7.96
12	8.26	28	8.36
13	8.31	29	8.10
14	8.52	30	8.21
15	8.25	31	8.21
16	8.26	32	8.21

Mean Value, $\bar{I}$ = 8.25 mg/Tablet

Estimate of Standard Deviation, S = 0.16 mg/Tablet

TABLE 2 - TITRATABLE IODINE FOR UNPOUCHED BLISTER SHEET SAMPLES TESTED FIVE DAYS AT 115°F AND 100 PERCENT RH

Sample No.	I (mg)	Sample No.	I (mg)
1 (12 tablets)	8.15	16	8.01
2	8.47	17	7.84
3	7.74	18	7.89
4	7.74	19	7.96
5	7.74	20	8.05
6	8.05	21	8.21
7	7.90	22	8.01
8	8.15	23	7.96
9	7.89	24	7.96
10	7.84	25	8.05
11	7.89	26	8.10
12	7.96	27	7.89
13	7.96	28	7.09
14	8.01	29	7.69
15	7.84	30	7.96
		31	7.89

Mean Value $\bar{I}$ = 7.95 mg/Tablet

Estimate of Standard Deviation S = 0.16 mg/Tablet

TABLE 3 - VACUUM LEAKAGE TESTS
(5 min., 20 in. Hg)

Sample No.	Sample Size	Sheet Failures No. & Percent	Blister Failures No. & Percent
1	20 sheets/ (240 blisters)	2 (10%)	6 (2.5%)
2	20 sheets/ (240 blisters)	1 (5%)	1 (0.42%)
3	20 sheets/ (240 blisters)	3 (15%)	4 (1.67%)
4	20 sheets/ (240 blisters)	1 (5%)	1 (0.42%)
5	20 sheets/ (240 blisters)	2 (10%)	2 (0.83%)
6	20 sheets/ (240 blisters)	2 (10%)	3 (1.26%)
7	20 sheets/ (240 blisters)	2 (10%)	2 (0.83%)
8	20 sheets/ (240 blisters)	5 (24%)	11 (4.6%)
TOTAL	160 sheets/ (2880 blisters)	18 (11.3%)	30 (1.04%)

Discussion

Deterioration of the tablet when a naked blister sheet is subjected to a wet-humid environment (i.e. 115°F @ 100 percent RH) is readily apparent by the reduction in the mean titratable iodine content per tablet from 8.25 mg to 7.95 mg. The deterioration was also evident by the presence of a large number of yellow spots on the tablets. Although the titratable iodine is still within specifications (i.e. 7.6 mg/tablet) after humidity testing, the deterioration is known to continue with time, hence, the necessity of a moisture resistant pouch overwrapper. It is interesting to note that an estimate of the standard deviation of titratable iodine among samples is 0.16 mg/tablet for both groups (Tables 1 and 2) of samples. Belief is that the major cause of this dispersion is attributed to variations in tablet size, (weight and thickness measurements among individual tablets have shown differences up to 15 percent between extremes). Other factors which probably contribute to variations among samples are listed below:

1. Test measurement errors.
2. Different periods of exposure to air among tablets when they were being transferred from bottles to blister sheets.
3. Chemical inconsistencies among the tablets.

4. Packaging variations among samples such as material porosity and seal integrity.

The vacuum leakage tests showed that 11.3 percent of the blister sheets had one or more leakage failures and 1.04 percent of the individual blisters failed by seal leakage. Vacuum test failures are attributed to variations in heat sealing parameters during production sealing on the Sentinel F-20 Heat Sealer. It was difficult to tell before vacuum leakage tests whether a seal would be defective.

Visual examination of test samples using a polarmeter and a 10X magnifying glass revealed no seal holes and for the most part, uniform seals for the entire sample quantity of 180 blister sheets.

PACKAGE EVALUATION

Improved Features

The blister sheet and pouch overwrapper package developed for the iodine water purification tablet represents a substantial improvement over the present fifty tablet bottle. Its major advantages over the bottle are manifested in the following features:

a. The individual sealing of tablets, which eliminates air exposure of tablets until used,

b. Individual sealing of tablets, which reduces probability of tablet breakage during rough handling,

c. The tablet potency color match,

d. A more convenient flat shape, and

e. A weight reduction from 26 grams to 9 grams per package.

The pouch overwrapper has the primary function of guarding against the intrusion of moisture during storage. The pouch material, which is being used extensively by the armed services, is virtually 100 percent reliable in this respect because of its aluminum foil substrate, and it has demonstrated excellent heat sealability. Once the pouch is opened, however, its effectiveness as a moisture barrier is greatly reduced. The blister sheet, once the pouch is opened, is expected, under most conditions, to offer sufficient protection to the tablet during a typical operational usage period.

Environmental Tests

Fifty shipping cartons of the pilot production quantity of the package were sent on 30 September 1970 to the U. S. Army Natick Laboratories for simulated environmental testing. Natick has since published an interim report analyzing the package in comparative testing with the present 50 tablet bottle from a storage protection standpoint. The tests described in the report consisted of subjecting the pouched and unpouched blister sheets and 50 tablet bottles to a variety of environmental test conditions for one, two, and three month periods, thereafter determining tablet deterioration in terms of titratable iodine content and solubility.

Data presented in the Natick report[4] established certain basic trends. These were:

a. The naked blister sheets offer better protection at 140°F than the present 50 tablet bottle and the titratable iodine within the blister sheets is not diminished over the three month test period.

b. The blister sheet and pouch overwrapper passed rough handling tests. Rough handling had no effect on tablet potency.

c. Pouched blister sheets failed the 140°F high temperature test, as well as storage at 100°F/95% RH.

d. Both the bottle and flexible package offer sufficient protection to the tablet at temperatures between 72°F and -20°F.

CRC conducted an independent set of tests to determine the reason why unpouched blister sheets passed titration testing after extended storage at 140°F, while serious tablet deterioration occurred when the blister sheets were sealed within the pouch. Through an extensive process of elimination, it was determined that the cause of failure was moisture entrapped in the cellulose acetate instruction label, which by its nature is very hygroscopic. When the naked blister sheet was heated, the moisture was permitted to escape into the air; however, in the close confines of the pouch, the moisture engulfed the blister sheets in a hot-moist environment which caused rapid deterioration of the tablets. Subsequent testing demonstrated that this problem could be entirely eliminated simply by pre-heating the labels to the blister sheets. When this was done, no discoloration of tablets occurred when tested at 140°F for three weeks; and titration test results gave 8.10 mg I_2/tablet with total solubility of all tablets in less than 300 seconds. Unfortunately, this precaution was not considered during the pilot production run; therefore, all of those pouched blister sheets will probably indicate tablet deterioration when tested at elevated temperatures.

Although these tests are not conclusive because of their limited scope, they are very encouraging since packaging technique and not the package itself appears to be at fault. It should be

noted also that the cellulose acetate label was selected because of the limited production quantity, and would probably be replaced in mass production with a cheaper less hygroscopic material.

It should be recognized that the cellulose acetate label, which has contributed to tablet failures, may be used to give added tablet protection once it is predried and sealed in the pouch. If this is done, it would itself absorb any residual moisture which may by chance or otherwise enter the pouch.

Mass Production Feasibility

The package could be made of higher quality and at reduced cost when mass produced. In mass production, there would be economic justification for expenditures for improvements in fabrication machinery, and research into less expensive packaging materials. A number of the anticipated improvements were discussed in the main report, including improved heat sealing of Aclar, a reduction in scrap, a cheaper color match label, and automatic pouch filling and sealing equipment. In addition to these points, Allied Chemical has indicated that the temperamental nature of forming blisters from Aclar has virtually been eliminated by recent advances in machinery which pressure forms blisters. It also is anticipated that packaging operations would be conducted within an environment substantially below the present permissible specification ($80^{\circ}F$ @ 30 percent RH). This factor is expected to reduce significantly the rate of tablet failure during storage. Improved quality control procedures would assure the quality of tablets prior to packaging, the maintenance of a low humidity packaging environment during packaging, and a simpler method of inspecting the integrity of blister sheet and pouch seals.

With the present packaging system, it is estimated that a manufacturer could mass produce the package for a unit price of approximately $0.20. After one or two years of operation, it

is expected that improvements in materials and packaging technique could reduce this cost to perhaps $0.10 per package, a price which is comparable to the present 50-tablet bottle.

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2. Brown, D. F. and Derick, C. T., "A Blister Sheet and Pouch Overwrapper Package for the Iodine Water Purification Package," Columbia Research Corporation Report No. 102-1 (October 1970).

3. Pioneering Research Laboratory Lab Report No. 70-F-8 of 4 March 1971.

4. Columbia Research Corporation letter of 7 May 1971 entitled "Review of Pioneering Research Laboratory Lab Report No. 70-F-8" to U. S. Army Land Warfare Laboratory.

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13. ABSTRACT

The development and pilot production of a blister sheet and pouch overwrapper package for the iodine water purification tablet is described. The blister sheets are fabricated from a fluorohalocarbon film containing 12 tablets with each tablet isolated by a heat sealed gridwork. A pressure sensitive label adheres to each blister sheet. This label is fabricated so that use instructions are on one side and a tablet gray color match is on the adhesive side to act as a tablet potency indicator. The pouch overwrapper is fabricated from a laminated film of Mylar-aluminum foil polyolefin and is designed to contain two blister sheets. Advantages of the package over the present 50 tablet glass bottle are 1) individually isolated tablets 2) immediate field indication of tablet potency 3) a more convenient shape (flat) 4) a reduction in weight (60%) and 5) more legible instructions for use.